

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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	01 DEC 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/8/2021
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10081928]
2.	Birth Date:	(b) (6) 2007
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:	

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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 _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Jan/8/2021
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:** 10081928**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Attention deficit hyperactivity disorder]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sulfa allergy]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Jan/8/2021
2.	Weight:	[163.0]
3.	Unit:	LB
4.	Height:	[64.5]
5.	Unit:	in
6.	Body Mass Index:	[27.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.0]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**eCRF Audit Trail History****Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/8/2021
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:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jan/8/2021
2.	Randomization Number:	[26362]
3.	Randomization Group:	[]

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRDZ57]
5.b	Sample ID	[BRDZ58]
5.c	Sample ID	[BSCBBZ]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRF58Y]
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:	Jan/8/2021 15:23
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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	--	---

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Jan/15/2021
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/29/2021
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:23

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/29/2021
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:	

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRKB2L]
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:	Jan/29/2021 14:26
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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/26/2021
2.	Erroneous Visit	

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Form Comments](#)[eCRF Audit Trail History](#)**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Feb/5/2021	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Feb/5/2021	Comments
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Feb/5/2021	Comments
3.	Injection Site Location:	DELTOID MUSCLE	Comments
4.	Injection Site Body Side:	LEFT	Comments
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	NO	Comments
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	NO	Comments
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	NO	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRNJJS]
5.b	Sample ID	[BRNJJT]
5.c	Sample ID	[BPCDNM]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Jan/18/2021

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: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Jan/18/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/18/2021
2.	Date of First Symptom Started:	Jan/16/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/22/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Jan/18/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

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Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.a	Symptoms - Other Text:	[fatigue]
5.b	Symptoms - Other Text:	[runny nose]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Jan/18/2021**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:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Jan/18/2021

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: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRF0MW]
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Jan/18/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT

Jan/18/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[eCRF Audit Trail History](#)

Respiratory Treatment

1.	What is the treatment Identifier?	Not Done _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done _____	Comments
3.	Treatment:	Not Done _____	Comments
4.	Treatment:	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Jan/18/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE
Jan/18/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:24

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/18/2021

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/18/2021

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b	Sponsor ID:	Not Done []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Done []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/18/2021

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.d	Sponsor ID:	Not Done []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Done []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/18/2021

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.f	Sponsor ID:	Not Done []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Done []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:28

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result :	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/18/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Laboratory Data Hematology

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/18/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b	Sponsor ID:	Not Done []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Done []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/18/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.d	Sponsor ID:	Not Done []	Comments
	Test:	Platelets_PX5	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Done []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/18/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.f	Sponsor ID:	Not Done []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Done []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/18/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.h	Sponsor ID:	Not Done []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments
5.i	Sponsor ID:	Not Done []	Comments
	Test:	Basophils_PX610	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/18/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.j	Sponsor ID:	Not Done []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Done []	Comments
	Not Done:	Not Done	Comments
	LNMT	Not Done Low [] High [] Unit	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:25

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VITAL SIGNS - COVID

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Done	Not Done	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Jan/18/2021

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Systolic:	Not Done _____ []	Comments
	Diastolic:	Not Done _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Done _____ []	Comments
	Heart Rate in beats/minute:	Not Done _____ []	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:31

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Date:	Vital Signs Details		Form Instance
1.	Not Done	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Done	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Jan/18/2021

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	SPO2 Pulse Oximetry %	Not Done _____ []	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Jan/18/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Done _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:55

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Jan/18/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[Form Comments](#)

[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Done _____ []	Comments
2.	Category:	Not Done _____	Comments
3.	Concomitant Medications Pre-specified:	Not Done _____	Comments
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).	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING

Jan/18/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[eCRF Audit Trail History](#)

Imaging

1.	Date of Assessment:	Not Done _____ //	Comments
2.	Location of Assessment:	Not Done _____	Comments
3.	Type of Imaging Exam:	Not Done _____	Comments
4.	Assessment:	Not Done _____	Comments

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/18/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/18/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/18/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRNSTP]
5.b	Sample ID	[BRNSTR]
5.c	Sample ID	[BPCDMS]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT - REPEAT SWAB

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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 Version: 10-Oct-2020 15:57

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	urticaria multiple sites	Jan/10/2021 UNK: UNK	NO End Date Time: Jan/22/2021 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[urticaria multiple sites]
4.	Start Date Time:	Jan/10/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 UNK:UNK
6.	Toxicity Grade:	1
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?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Medication Error

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

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (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: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**Concomitant Medications**

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

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: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Concomitant Medications

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

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: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Radiation Treatment

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

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: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jan/18/2021 Contact Outcome: VISIT ARRANGED
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form: VITAL SIGNS - TEMP

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/18/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/18/2021**Form Version:** 14-Jan-2021 02:20**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Jan/18/2021
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	LEFT

Reaction

4.a	Reaction:	REDNESS
	Reaction Present:	NO
4.b	Reaction:	SWELLING
	Reaction Present:	NO

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	NO
5.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	NO
5.c	Symptom:	HEADACHE
	Symptom Present:	NO
5.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	NO
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Symptom Present:	NO
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN
	Symptom Present:	NO

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 14-Jan-2021 02:20

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.h	Symptom:	CHILLS
	Symptom Present:	NO

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 20-Feb-2021 02:16

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form Version:** 20-Feb-2021 02:14**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Not Started**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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 Version:** 10-Dec-2020 02:26**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Not Started**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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?	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Contact Outcome

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

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form Version:** 10-Oct-2020 16:01**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - MONTH 6**Form Status:** Not Started**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Contact Outcome**

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/18/2021
2.	Erroneous Visit	

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/18/2021
----	--------------	--

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[see COVID_A1]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRNSZ6]
-----	-----------	----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/04/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/4/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Visit on Mar/04/2021**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA00773]
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Feb/26/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 10-Dec-2020 02:27

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/26/2021

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Timothy Jennings	Approved	Mar-11-2021 13:22:50 (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 Version: 10-Oct-2020 16:00

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-08-2021 14:05:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.a	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.a	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.b	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.b	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.c	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
2.c	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.d	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.d	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.e	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.e	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.f	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.f	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.g	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
2.g	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.h	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.h	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5.a	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.a	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5.b	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.b	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5.c	Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.c	Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
6	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/18/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)

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Header Text: c4591001

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Site No: 1008

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8	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen, Verified

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9	Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Form Status: Data Complete, Frozen, Verified

Site No: 1008

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Header Text: c4591001

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3	Jan-18-2021 14:56:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments**Form Version:** 10-Dec-2020 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)

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4	Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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5.a	Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments**Form Version:** 10-Dec-2020 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)

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5.a	Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001			
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5.b	Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments**Form Version:** 10-Dec-2020 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)

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5.d	Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)

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Form: CASEBOOK SIGNATURE FORM - Signature History

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Timothy Jennings	Approved	Mar-11-2021 13:22:50 (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.

(b) (6)	N/A	Feb-25-2021 07:47:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Timothy Jennings	Approved	Feb-22-2021 22:10:41 (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.

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jan-08-2021 14:02:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 14:02:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-08-2021 14:02:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Subject ID

Date	Location	User	Value	Reason
Jan-08-2021 14:01:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10081928	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jan-08-2021 14:01:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 2007	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jan-08-2021 14:02:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jan-08-2021 14:02:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 14:02:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 14:02:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jan-08-2021 14:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-08-2021 14:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-08-2021 14:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Jan-08-2021 14:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Attention deficit hyperactivity disorder Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Jan-08-2021 14:37:31 (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
Jan-08-2021 14:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Attention deficit hyperactivity disorder	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Jan-08-2021 14:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Jan-08-2021 14:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-08-2021 14:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Anxiety Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Jan-08-2021 14:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 14:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anxiety	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Jan-08-2021 14:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Jan-08-2021 14:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-08-2021 14:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Sulfa allergy	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Start Date:	UNK/UNK/2014	
			Ongoing:	YES	

1.c Line/MH Number:

Date	Location	User	Value	Reason
Jan-08-2021 14:38:06 (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
Jan-08-2021 14:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sulfa allergy	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Jan-08-2021 14:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Jan-08-2021 14:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-08-2021 14:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HI V POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/8/2021	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 163.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 64.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 27.5	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

7.a

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.0 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-08-2021 14:36:53 (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
Jan-08-2021 14:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-08-2021 14:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-08-2021 14:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:23

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			d Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
--	--	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-08-2021 14:36:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Randomization Date :

Date	Location	User	Value	Reason
Jan-08-2021 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jan-08-2021 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 26362	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 15:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-08-2021 15:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-08-2021 15:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 15:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 15:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 15:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDZ57	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-08-2021 15:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDZ57	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-08-2021 15:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDZ58	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 15:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDZ58	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-08-2021 15:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSCBBZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 15:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSCBBZ	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 15:07:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-08-2021 15:07:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-08-2021 15:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 15:07:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 15:07:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 15:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRF58Y	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-08-2021 15:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRF58Y	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/8/2021 15:23	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

090177e196b72786\Final\On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

7. Route:

Date	Location	User	Value	Reason
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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
Jan-08-2021 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jan-08-2021 14:03:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 15:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sympt NO oms present on the last day t he Subject Diary was complet ed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGU E	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	YES Ongoing? NO Stop Date: Jan /15/ 2021	
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2.b Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Ongoing? NO Stop Date: Jan/15/2021	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.c Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH ILL S Were fever or systemic sympt oms present on the last day t he Subject Diary was comple ted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUSCLE P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOIN T PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-04-2021 08:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Changed Information
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: REDNES : S Were injection site reac YES tions present on the las Ongo t day the Subject Diary g? was completed?: NO Stop Date: Jan/ 15/ 202 1	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 02:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Feb-04-2021 08:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-04-2021 08:16:49 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Time (US & Canada)		(b) (4), (b) (6)		
Feb-04-2021 03:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ2: Per diary records, Redness is only "1" unit recorded on last day 14-Jan-2021. However, Redness greater than 4 caliper units is considered as Grade 1. Please review and consider to update response as appropriate. Else clarify. Thank you
Feb-03-2021 09:07:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	any symptoms reported on last day of diary are to be followed with an end date, regardless of severity. redness does not meet AE criteria per ecrf guidelines per PI. but is present on last day of diary
Feb-03-2021 02:38:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ1: Redness greater than 4 caliper units on the last day is considered as Grade 1. Per e-Diary records, Redness is only "1" units. However, Last day in Inform is marked as 'Yes'. Please review and consider to update. Thank you
Feb-02-2021 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per ed diary redness measuring 1 is present and moderate fatigue, not sure what your looking at

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-02-2021 04:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, Day 7 is the last day reported on 14-Jan-2021 & REDNESS not present on Last day however inform is entered with 'Yes' for the same. Please verify and update. Else, clarify. Thanks
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Jan/15/2021	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 15:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-29-2021 15:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.6 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Jan-29-2021 15:12:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FOREHEAD	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:23

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:25 (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
Jan-29-2021 15:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-29-2021 15:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-29-2021 15:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:23

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			d Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 14:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 14:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-29-2021 14:07:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 14:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 14:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-29-2021 14:07:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKB2L	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-29-2021 14:07:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRKB2L	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021 14:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

7. Route:

Date	Location	User	Value	Reason
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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
Jan-29-2021 15:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)***I. Date of Visit***

Date	Location	User	Value	Reason
Mar-03-2021 12:39:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 3: Closed	Response satisfies query
Mar-03-2021 11:27:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Mar-03-2021 07:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Mar-03-2021 07:52:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-03-2021 07:52:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Mar-03-2021 07:52:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-03-2021 07:52:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/26/2021	Transcription Error
Mar-02-2021 23:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	CLINQUERY: Samples page of V3 reports collection date of 26Feb21. Please review if this DOV page requires updating (date

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

				updated and 'erroneous' mark to be removed); else clarify discrepant dates
Mar-02-2021 23:10:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	DM: Erroneous visit is marked. Please confirm if this visit occurred. If yes, kindly untick erroneous visit button. If not occurred, kindly erase data from rest of forms and mark the forms as Not Done/Not Applicable at form level comment or else clarify.
Mar-02-2021 07:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Candidate	CLINQUERY: Samples page of V3 reports collection date of 26Feb21. Please review if this DOV page requires updating (date updated and 'erroneous' mark to be removed); else clarify discrepant dates
Feb-19-2021 13:52:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Feb-19-2021 07:54:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	this visit was not performed
Feb-19-2021 03:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

				any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-18-2021 14:05:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-18-2021 13:58:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/18/2021	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-03-2021 07:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-18-2021 14:05:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Ent ry: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Ent ry:	Initial Entry
Feb-19-2021 13:52:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 07:53:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this visit was not performed
Feb-19-2021 01:48:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7314792;Were medications to treat fever/pain given on the last day the Subject Diary was completed? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ry: Not Applicable	Initial Entry
Feb-18-2021 14:06:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ry:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FEV ER	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Feb-18-2021 14:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Canada)				
Feb-19-2021 13:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Feb-19-2021 07:53:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	this visit was not performed
Feb-19-2021 01:50:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7314632;Symptoms Occur? are not expected to be Unknown or Not Applicable. Please review and update appropriately for all symptoms or clarify.
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry
Feb-18-2021 14:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry

2.b

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Mar-01-2021 08:15:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Feb /5/ 2021	Transcription Error
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Feb-18-2021 14:06:47 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT	Transcription Error

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Time (US & Canada)		(b) (4), (b) (6)	IG UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IG UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.b Symptom:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 02:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Mar-01-2021 08:15:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-01-2021 08:15:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: : YES Ongoing? NO Stop Date: Feb/5/ 2021	Transcription Error
Mar-01-2021 02:00:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	eDiary: Per eDiary records, "Fatigue occurrence" is reported on Last day (Day 7) however the last day in Inform CRF data is entered as No for the same. Please verify

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

				and update. Else, clarify. Thanks (b) (4)
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Applicable	Initial Entry
Feb-18-2021 14:06:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Mar-01-2021 08:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE	Transcription Error

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Feb/5/2021</p>	
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: HEA DA CHE</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: HEA DA CHE</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p>	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: HEA DAC HE</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable</p>	Initial Entry
Feb-18-2021 14:07:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: HEA DA CHE</p>	Transcription Error

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.c Symptom:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 02:13:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Mar-01-2021 08:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-01-2021 08:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Feb/5/ 2021	Transcription Error
Mar-01-2021 01:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	eDiary: Per eDiary records, "Headache occurrence" is reported on Last day (Day 7) however the last day in Inform CRF data is entered as No for the same. Please verify

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

				and update. Else, clarify. Thanks (b) (4)
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Applicable	Initial Entry
Feb-18-2021 14:07:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CHI LLS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Feb-18-2021 14:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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2.d

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH ILL S Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-18-2021 14:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MITI NG Were fever or systemic sy Not mptoms present on the las Appli t day the Subject Diary wa cable s completed?:	Initial Entry
Feb-18-2021 14:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym NO ptoms present on the last d ay the Subject Diary was c ompleted?:	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
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Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.e Symptom:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-18-2021 14:07:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

			HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Feb-18-2021 14:07:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
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Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.f Symptom:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Feb-18-2021 14:07:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WORSENED MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Time (US & Canada)		(b) (4), (b) (6)	<p>WORSEN ED MUS CLE PAIN</p> <p>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</p>	
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSEN ED MUS CLE PAIN</p> <p>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</p> <p>Not Appli cable</p>	Initial Entry
Feb-18-2021 14:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSEN ED MUS CLE PAIN</p> <p>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</p>	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSEN ED MUS CLE PAIN</p> <p>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</p> <p>NO</p>	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
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Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.g Symptom:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-18-2021 14:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Mar-01-2021 08:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSENERED J OINT PAIN	Transcription Error

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Feb/5/ 2021	
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED JOIN T PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED JOIN T PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: :	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED JOIN T PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Feb-18-2021 14:09:07 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR	Transcription Error

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Time (US & Canada)		(b) (4), (b) (6)	<p>WORSEN ED JOIN T PAIN</p> <p>Were fever or systemic symptoms present on t he last day the Subject Diary was completed? :</p>	
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR WORSEN ED JOIN T PAIN</p> <p>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed? :</p>	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.h Symptom:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 02:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Mar-01-2021 08:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-01-2021 08:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Feb/5/2021	Transcription Error

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
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Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-01-2021 01:59:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: O pened	eDiary: Per eDiary records, "New or worsened joint pain occurrence" is reported on Last day (Day 7) however the last day in Inform CRF data is entered as No for the same. Please verify and update. Else, clarify. Thanks (b) (4)
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-18-2021 14:09:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: y: NO	Initial Entry
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3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-18-2021 14:06:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-18-2021 14:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the S ubject Diary was completed ?:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RED NES S Were injection site reactio ns present on the last day t he Subject Diary was comp leted?:	Initial Entry
Feb-18-2021 14:08:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the S ubject Diary was completed ?:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Initial Entry
Feb-19-2021 13:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Feb-19-2021 07:54:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	this visit was not performed
Feb-19-2021 01:51:49	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Open	DMW7314712;Reactions Occur? are not expected

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Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-06:00) Central Time (US & Canada)			ned	to be Unknown or Not Applicable. Please review and update appropriately for all reactions or clarify
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not A pplica ble	Initial Entry
Feb-18-2021 14:08:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction s present on the last day th e Subject Diary was compl eted?:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
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Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLIN G Were injection site reactions present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Feb-18-2021 14:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Feb-18-2021 14:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN A T INJE CTION SITE Were injection site react NO ions present on the last day the Subject Diary w as completed?:	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN A T INJE	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			CTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN A T INJE CTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Feb-18-2021 14:08:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN A T INJE CTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN A T INJE CTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Feb-26-2021 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-18-2021 14:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-18-2021 14:08:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-18-2021 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-26-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-26-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-26-2021 15:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-26-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 15:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRNJJS	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-26-2021 15:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRNJJS	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-26-2021 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRNJJT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRNJJT	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-26-2021 15:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPCDNM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 15:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPCDNM	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Jan/18/2021**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:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-18-2021 14:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-18-2021 14:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-18-2021 14:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/18/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-18-2021 14:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/18/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/16/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 14:17:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/22/2021	New Information
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**4.c Symptoms:**

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNE SS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom NO Present:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/18/2021 Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**4.e Symptoms:**

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms: NEW LOSS OF TAS TE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW LOSS OF TASTE OR SMEL L	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms NEW OR INCREASE : D SORE THROAT	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Symptom YES Present:	
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4.g Symptoms:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

(US & Canada)

Symptoms: VOMITING

Symptom Present: NO

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-18-2021 14:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:54:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: fatigue	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fatigue	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-18-2021 14:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: runny nose	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-18-2021 14:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: runny nose	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/18/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/18/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

7. Test Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Jan-18-2021 14:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-18-2021 14:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-18-2021 14:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-18-2021 14:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: SWAB PFE PERFORMED	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-18-2021 14:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-18-2021 14:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-18-2021 14:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 14:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRF0MW	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-18-2021 14:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRF0MW	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/18/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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I.a

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENC Y ROOM Occurrence of Visit NO s or Contacts:	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/18/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Type of Practitioner: URGENT	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
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Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

(US & Canada)			CARE Occurrence of Visits or Contacts: NO	
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/18/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-20-2021 09:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or C NO ontacts:	Transcription Error
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practiti OTHER oner: Occurrence of V YES isits or Contacts <i>Number of Visi</i> : <i>ts or Contacts:</i> 1	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/18/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**1.f Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-20-2021 09:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-20-2021 09:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Transcription Error
Jan-20-2021 09:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	"Other" is selected , however other specific item is blank. Please review and update as appropriate.
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Jan-20-2021 12:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Jan-20-2021 09:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-20-2021 09:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Transcription Error
Jan-19-2021 13:39:27	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CINQUERY: Study

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/18/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		site telehealth/in-person study site visits should not be captured as part of this CRF. Any additional healthcare services outside of protocol study site visits are captured here. Please confirm data is entered appropriately per CCG 8.35
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EVAL BY PI/SITE STAFF	Initial Entry

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

Date	Location	User	Value	Reason
Jan-18-2021 14:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
Jan/18/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-18-2021 14:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-18-2021 14:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Jan/18/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-18-2021 14:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 2	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
Jan/18/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-18-2021 14:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Lab Normal Range:	Not Done	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

(US & Canada)			er:	e	
			Test::	Not Done	
				e	
			Result::	Not Done	
				e	
			Not Done::	Not Done	
				e	
			Lab Normal Range:	Not Done	
				e	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Lab Normal Range:	Not Done	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

(US & Canada)			er:	e	
			Test::	Not Don e	
			Result::	Not Don e	
			Not Done::	Not Don e	
			Lab Normal Range:	Not Don e	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.h

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/18/2021 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-18-2021 14:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/18/2021**Form Version:** 10-Dec-2020 02:25**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-18-2021 14:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-18-2021 14:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respir Not Done ations/minute: one Heart Rate in beats/minut Not Done e: one	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:38	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/18/2021

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Done	
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-18-2021 14:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Record Identifier:: Not Done Oxygen Saturation: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-18-2021 14:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-18-2021 14:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History
Jan/18/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-18-2021 14:58:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-18-2021 14:58:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-18-2021 14:58:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-18-2021 14:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-18-2021 14:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-18-2021 14:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	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 the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-18-2021 14:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-18-2021 14:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/18/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-18-2021 14:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Jan/18/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-18-2021 14:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-18-2021 14:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-18-2021 14:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-18-2021 14:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/18/2021

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-18-2021 13:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/18/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-18-2021 13:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/18/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-18-2021 13:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-18-2021 13:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-18-2021 13:58:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 13:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-18-2021 13:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-18-2021 13:58:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRNSTP	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/18/2021

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-18-2021 13:58:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRNSTP	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-18-2021 13:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRNSTR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 13:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRNSTR	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-18-2021 13:59:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPCDMS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 13:59:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPCDMS	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (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-12-2021 09:17:52 (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
Jan-12-2021 16:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-12-2021 16:15:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed subject has not had exposures to sulfa containing drugs since vaccination
Jan-12-2021 16:05:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm that participant has not had exposures to sulfa-containing drugs since vaccination.
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: urticaria multiple sites	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/10/2021 UNK:UNK	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

(US & Canada)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-29-2021 15:13:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/22/2021 UNK:UNK	New Information
Jan-21-2021 19:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 09:09:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per unplanned visit, urticaria states much improving but has not ended/resolve
Jan-19-2021 17:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLin: per unplanned visit 18-Jan2021, no ongoing urticaria was reported. please update AE form to reflect end date of urticaria.
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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).

090177e196b72786\Final\On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-29-2021 15:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-29-2021 15:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Jan-29-2021 15:13:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE urticaria multiple sites: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 09:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 14:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Jan/18/2021	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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I. Assessments

Date	Location	User	Value	Reason
Jan-18-2021 14:52:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Jan-18-2021 14:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/18/2021

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Contact Type:

Date	Location	User	Value	Reason
Jan-18-2021 14:52:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:52:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Jan-18-2021 14:52:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Jan/18/2021 Contact Outcome: VISIT ARRANGED	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/18/2021**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:22**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081928**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-18-2021 14:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/18/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-18-2021 14:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.1 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-18-2021 14:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jan-18-2021 14:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-18-2021 14:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081928

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-18-2021 14:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: FOREHEAD	Initial Entry
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Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/18/2021**Form Version:** 14-Jan-2021 02:20**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/18/2021	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: LEFT	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Reaction:: REDNESS Reaction Present:: NO	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: REDNESS	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 14-Jan-2021 02:20

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

(US & Canada)

4.b

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: SWELLING Reaction Present:: NO	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: PAIN AT INJECTI ON SITE Symptom Pre NO sent::	Initial Entry

5.a Symptom:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
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090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 14-Jan-2021 02:20

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE/TIRED NESS Symptom Present:: NO	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE Symptom Present:: NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 14-Jan-2021 02:20

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.c Symptom:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITING Symptom Present:: NO	Initial Entry

5.d Symptom:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRHEA Symptom Present:: NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/18/2021**Form Version:** 14-Jan-2021 02:20**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**5.e Symptom:**

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: DIARRHEA	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: NEW OR WORSENE D MUSCLE PAIN Symptom NO Present::	Initial Entry

5.f Symptom:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: NEW OR WORSENE D JOINT PAIN	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/18/2021

Form Version: 14-Jan-2021 02:20

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Symptom P NO resent::	
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5.g Symptom:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: CHILLS Symptom Present:: NO	Initial Entry

5.h Symptom:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: CHILLS	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Jan-18-2021 14:53:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-18-2021 14:04:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-18-2021 14:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Feb-18-2021 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-18-2021 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-18-2021 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Feb-18-2021 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: see COVID_A1	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-18-2021 13:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-18-2021 13:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-18-2021 13:49:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 13:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-18-2021 13:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-18-2021 13:49:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRNSZ6	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-18-2021 13:49:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRNSZ6	Initial Entry

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/04/2021

Form Version: 14-Jan-2021 02:22

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 15:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/4/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Mar-04-2021 15:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK2	Initial Entry

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/04/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-04-2021 15:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-04-2021 15:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-04-2021 15:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 15:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-04-2021 15:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-04-2021 15:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: AA00773	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 - Unscheduled
Visit on Mar/04/2021

Form Version: 10-Oct-2020 15:57

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Mar-04-2021 15:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: AA00773	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-26-2021 13:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/26/2021	Initial Entry
Feb-25-2021 07:47:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-18-2021 13:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/18/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-26-2021 13:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry
Feb-25-2021 07:47:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-18-2021 13:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-26-2021 13:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry
Feb-25-2021 11:14:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Feb-25-2021 07:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Feb-25-2021 07:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-24-2021 23:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: EOT page is marked as COMPLETED but V3 (month follow up post vax 2) is not yet completed per CRF. Please review and update as appropriate
Feb-23-2021 07:39:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: EOT page is marked as COMPLETED but V3 (month follow up post vax 2) is not yet completed per CRF. Please review and update as appropriate
Feb-18-2021 13:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081928**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Feb-26-2021 13:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Feb-25-2021 07:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Transcription Error
Feb-18-2021 13:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jan-08-2021 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jan-08-2021 14:02:39 (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-26-2021 13:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/26/2021	Initial Entry
Feb-25-2021 07:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/8/2021	Transcription Error
Feb-25-2021 07:47:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/8/2021	Transcription Error
Feb-18-2021 13:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/18/2021	Initial Entry
Jan-08-2021 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Jan-08-2021 14:02:39
(UTC-06:00) Central Time
(US & Canada)

ACV0PFEINFP6000

auto calc
(autocalc)

Data Entry:
Jan/8/2021

Initial Entry

090177e196b72786\Final\Final On: 06-Apr-2021 19:09 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081928

Generated By: (b) (4)

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): 06-Apr-2021 15:36

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I. Casebook Signature

Date	Location	User	Value	Reason
Feb-18-2021 13:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Click Here to Enable	Initial Entry