

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[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

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/29/2020
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**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form:** DEMOGRAPHY**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Demography**

1.	Subject ID	[11311287]
2.	Birth Date:	(b) (6) 2008
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/29/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Dec/29/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[acne]
	Start Date:	Apr/UNK/2020
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[eczema]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[attention deficit hyperactivity disorder]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

1.d

Line/MH Number:	[4]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[depressive symptoms]
Start Date:	Oct/UNK/2020
Ongoing:	YES



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** HIV STATUS

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**HIV Status**

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

The subject is NOT known to be HIV POSITIVE

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34**eCRF Audit Trail History****Vital Signs**

1.	Date:	Dec/29/2020
2.	Weight:	[47.5]
3.	Unit:	kg
4.	Height:	[156.3]
5.	Unit:	cm
6.	Body Mass Index:	[19.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34**eCRF Audit Trail History****Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Dec/29/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Dec/29/2020
2.	Randomization Number:	[24580]
3.	Randomization Group:	[ ]

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR0F5K]
5.b	Sample ID	[BR0F5L]
5.c	Sample ID	[BS7XNG]

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9B8H]
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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**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:	Dec/29/2020 11:35
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:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

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

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[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/4/2021
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Jan/4/2021

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

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
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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VITAL SIGNS - TEMP**Form Version:** 14-Jan-2021 02:22**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34**eCRF Audit Trail History****Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/18/2021
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:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[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	[BP9B9P]
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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**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/18/2021 13:20
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:** DATE OF VISIT

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

**eCRF Audit Trail History**

**Date of Visit**

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

**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:** 1131 **Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287 **Subject Initials:** ---**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34[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?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Jan/24/2021
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
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

**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:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287 **Subject Initials:** ---**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/15/2021
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	[BTZPTV]
5.b	Sample ID	[BTZPTW]
5.c	Sample ID	[BKZ3C8]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** V4\_MONTH6\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**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:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001**Visit:** V5\_MONTH12\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**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:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** V6\_MONTH24\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/17/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Feb/17/2021
2.	Date of First Symptom Started:	Feb/16/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Feb/19/2021

**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?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

4.f

Symptoms:	NEW LOSS OF TASTE OR SMELL
Was symptom present?	NO

4.g

Symptoms:	NEW OR INCREASED SORE THROAT
Was symptom present?	NO

4.h

Symptoms:	DIARRHEA
Was symptom present?	NO

4.i

Symptoms:	VOMITING
Was symptom present?	NO

**Symptoms - Other**

5.

Symptoms - Other Text:	[ ]
------------------------	-----

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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[Form Comments](#)

[eCRF Audit Trail History](#)

### Microbiology Specimen

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

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/17/2021
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	[CV55276]
-----	-----------	-----------

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5-a	Sample ID	[CV55276]
-----	-----------	-----------

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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
----	--	----

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Respiratory Treatment

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[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:	1

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Dec-2020 02:24

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Dec-2020 02:24

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

### Lab Result

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 10-Dec-2020 02:28

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category f or Lab Tes t	Vendor Nam e (DERIVED )	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 10-Dec-2020 02:28

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

### Lab Result

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

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Vital Signs

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

### Vital Signs Details

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Vital Signs

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

### Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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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.	Start Date:	//
6.	Ongoing?	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	enlarge lymph nodes-neck(bilateral)	Jan/27/2021 UNK:UNK	NO End Date Time:  Feb/3/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	rhinorrhea	Jan/17/2021 UNK:UNK	NO End Date Time:  Feb/3/2021 UNK:UNK	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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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)	[enlarge lymph nods-neck(bilateral)]
4.	Start Date Time:	Jan/27/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/3/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[rhinorrhea]
4.	Start Date Time:	Jan/17/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/3/2021 UNK:UNK
6.	Toxicity Grade:	1



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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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	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON  
STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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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.	Date:	//

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS -  
PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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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?	

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1131    **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 11:34

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** Unplanned Vaccination -  
Unscheduled**Form:** VITAL SIGNS - TEMP**Form Version:** 20-Feb-2021 02:16**Form Status:** Not Started**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**Vital Signs**

1. Date: //

**Vital Signs Details**

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



**Header Text:** c4591001**Visit:** Unplanned Vaccination -  
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**Lab Urinalysis**

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

**Lab Result**

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

**Header Text:** c4591001**Visit:** Unplanned Vaccination -  
Unscheduled**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Not Started**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**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:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT

Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Date of Visit**

1.	Date of Visit	Feb/15/2021
2.	Erroneous Visit	ERRONEOUS VISIT

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Form Comments](#)

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	Not Applicable	<a href="#">Comments</a>
----	--------------	----------------	--------------------------

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Form Comments](#)[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ [ ]
----	-----------	--------------------------------

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Form Comments](#)[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ [ ]
----	-----------	--------------------------------



**Header Text:** c4591001

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Feb/15/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

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

Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Not Started

**Site No:** 1131      **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:34

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**Form Version:** 10-Dec-2020 02:27

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** DISPOSITION - FOLLOW-UP

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** SUBJECT STATUS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/15/2021



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**Casebook Signature Form**

1.	Casebook Signature	
----	--------------------	--

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA -  
Comments

**Form Version:** 10-Oct-2020 16:00

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Dec-29-2020 14:46:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
2	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
3	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
4	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
5	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
6	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
7	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
8	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
9	Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - Comments

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Feb-24-2021 12:16:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - Comments

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Feb-24-2021 12:16:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
2	Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
3	Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
4	Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Feb-24-2021 12:17:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Feb-24-2021 12:17:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
2	Feb-24-2021 12:17:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
3	Feb-24-2021 12:17:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
4	Feb-24-2021 12:17:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Dec-29-2020 14:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 14:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORT S	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Consent Was:**

Date	Location	User	Value	Reason
Dec-29-2020 14:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Dec/29/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Subject ID**

Date	Location	User	Value	Reason
Dec-29-2020 14:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11311287	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-29-2020 14:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2008	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Dec-29-2020 14:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-29-2020 14:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Dec-29-2020 14:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRIC AN AMERICAN	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-29-2020 14:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Dec-29-2020 14:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-29-2020 14:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-29-2020 14:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Dec-29-2020 14:50:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N</b> 1 <b>umber:</b> <b>Medical His</b> acne <b>tory Term:</b> <b>Start Date:</b> Apr/UN K/2020 <b>Ongoing:</b> YES	Initial Entry

**1.a Line/MH Number:**

Date	Location	User	Value	Reason
Dec-29-2020 14:50:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 14:50:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> acne	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.a Start Date:***

Date	Location	User	Value	Reason
Dec-29-2020 14:50:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/UNK/2020	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Dec-29-2020 14:50:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Dec-29-2020 14:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 2</b> <b>umber:</b> <b>Medical His</b> eczema <b>tory Term:</b> <b>Start Date:</b> UNK/U NK/201 9 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Dec-29-2020 14:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 14:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> eczema	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Dec-29-2020 14:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Dec-29-2020 14:50:59	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*I.c*

Date	Location	User	Value	Reason
Dec-29-2020 14:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 3 <b>H Num</b> <b>ber:</b> <b>Medical</b> attention def <b>History</b> icit hyperact <b>Term:</b> ivity disorde r <b>Start Da</b> UNK/UNK/ <b>te:</b> 2016 <b>Ongoing</b> YES :	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.c Line/MH Number:***

Date	Location	User	Value	Reason
Dec-29-2020 14:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 14:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> attention deficit hyperactivity disorder	Initial Entry

***1.c Start Date:***

Date	Location	User	Value	Reason
Dec-29-2020 14:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

***1.c Ongoing:***

Date	Location	User	Value	Reason
Dec-29-2020 14:52:51	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

***1.d***

Date	Location	User	Value	Reason
Dec-29-2020 14:55:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH</b> 4 <b>Number:</b> <b>Medical</b> depressi <b>History T</b> ve sympt <b>erm:</b> oms <b>Start Dat</b> Oct/UN <b>e:</b> K/2020 <b>Ongoing:</b> YES	Initial Entry
Dec-29-2020 14:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 4 <b>Number:</b> <b>Medical</b> depressi <b>History T</b> ve sympt <b>erm:</b> oms <b>Start Dat</b> Oct/UN <b>e:</b> K/2020 <b>Ongoing:</b>	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Dec-29-2020 14:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 14:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> depressive symptoms	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Jan-05-2021 13:58:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 15:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answer ed	per site physician subject meet all study criteria

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-04-2021 14:14:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Depressive symptoms is reported as a recent medical condition within the past year. Please confirm if subject meets Inc #3 or Exc #1 as per the PI's assessment, then update the CRF as appropriate.
Dec-29-2020 14:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/UNK/2020	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Dec-29-2020 14:55:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Dec-29-2020 14:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT k nown to be HIV POS ITIVE	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 47.5	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 156.3	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 19.4	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature:</b> 37.1	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Temperatu C re Unit:</b> <b>Temperatu ORAL re Locatio CAVIT n:: Y</b>	
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.1	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-29-2020  
14:58:53  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

auto calc  
(autocalc)

**Data Entry:**  
STUDY SITE

Initial Entry

**5. Specimen Type:**

**Date**

**Location**

**User**

**Value**

**Reason**

Dec-29-2020  
14:58:53  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

auto calc  
(autocalc)

**Data Entry:**  
URINE

Initial Entry

**6.a**

**Date**

**Location**

**User**

**Value**

**Reason**

Dec-29-2020  
14:58:53  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

auto calc  
(autocalc)

**Data Entry:**  
**Sponsor-** 113  
**Defined I**  
**dentifier:**  
**Test::** Choriogon  
adotropin  
Beta\_PX11  
3  
**Result::** NEGATIV  
E  
**Not Done**  
**::**

Initial Entry

**6.a Sponsor ID:**

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Dec-29-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24580	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-29-2020 14:58:04 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Dec-29-2020 14:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/29/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BR0F5 : K	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR0F5K	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-29-2020 14:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID</b> BR0F5 : L	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-29-2020 14:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BR0F5L	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID</b> BS7XN : G	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BS7XNG	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-29-2020 14:59:17 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Dec-29-2020 14:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/29/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BP9B8 : H	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-29-2020 14:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9B8H	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020 11:35	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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***1. Select appropriate response - Reactogenicity diary collection***

Date	Location	User	Value	Reason
Dec-29-2020 15:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGE NICITY E-DIARY C OLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-19-2021 09:48:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <b>Symptom::</b> F E V E R  Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary w as completed?:	Initial Entry

**2.a Symptom:**

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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Jan-21-2021 12:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> FATIG : UE	New 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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing? NO Stop Date: Jan/4/2021	
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> <b>Symptom::</b> FATIGUE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing? YES E S	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-22-2021 06:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Jan-21-2021 12:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-21-2021 12:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Jan/4/2021	New Information

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-21-2021 07:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per Diary records, 'FATIGUE' reported post Vaccination 1 is not ongoing through Vaccination 2. Please reconcile and consider to update stop date here. Else, clarify in query response. Thanks.
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  YES	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Jan-21-2021 12:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> HEAD : ACHE	New 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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing? NO Stop Date: Jan/4/2021	
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> <b>Symptom::</b> HEADACHE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing? YES Stop Date:	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**2.c Symptom:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-22-2021 06:23:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Jan-21-2021 12:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-21-2021 12:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Jan/4/2021	New Information

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-21-2021 07:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per Diary records, 'HEADACHE' reported post Vaccination 1 is not ongoing through Vaccination 2. Please reconcile and consider to update stop date here. Else, clarify in query response. Thanks.
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  YES	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C H I L L S	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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: VO	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

MI  
TI  
NG

Were fever or s NO  
ystemic sympt  
oms present on  
the last day the  
Subject Diary  
was completed  
?:

**2.e Symptom:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI A RR HE A  Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed ?:	Initial Entry
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**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**2.g**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUS CLE P AIN  <b>Were fever NO or systemic symptoms p resent on th e last day th e Subject Di ary was co mpleted?:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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History

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**2.g Symptom:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED 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
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED JOIN T PAI N	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

			Were fever NO or systemic symptoms p resent on th e last day th e Subject Di ary was com pleted?:	
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**2.h Symptom:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSEN ED JOINT PAIN	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-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Jan-19-2021	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

09:50:41  
(UTC-05:00)  
Eastern Time (US  
& Canada)

(autocalc)

DELTOID MUSCLE

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> D N ES S <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**5.a Injection Site Reaction:**

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG  <b>Were injection</b> NO <b>site reactions p</b> <b>resent on the l</b> <b>ast day the Su</b> <b>bject Diary wa</b> <b>s completed?:</b>	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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> PAI <b>Reaction::</b> N A T IN JEC TIO N SI TE	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2021 09:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 14-Jan-2021 02:22**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> <b>Temperature Core Unit:</b> <b>Temperature ORAL</b> <b>Record Location CAVIT</b> <b>Notes:: Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:23 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3006\Final\On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry
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**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> <b>::</b>	Initial Entry

**6.a Sponsor ID:**

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-19-2021 09:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-18-2021 16:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-18-2021 16:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-18-2021 16:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 16:58:03 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 16:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-18-2021 16:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9B9P	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-18-2021 16:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9B9P	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021 13:20	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 09:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-15-2021 12:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/15/2021	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:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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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-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <b>Symptom::</b> F E V E R  <b>Were fever or s N</b> <b>ystemic sympto O</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary w</b> <b>as completed?:</b>	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131 **Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287 **Subject Initials:** ---**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or s N</b> <b>ystemic sympto O</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary</b> <b>was completed?</b> :	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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**2.b Symptom:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE A D AC HE	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
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**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Feb-18-2021 12:25:18	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom: CHILL	New Information

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	: S <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing? NO Stop Date: January 24, 2021	
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> CHILL : S	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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	YES Ongoing?  NO  Stop Date:  Jan/ 1 8/ 2 0 2 1	
--	--	--	--	--	--

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**2.d Symptom:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2021 02:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Data updated by site.
Feb-18-2021 12:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-18-2021 12:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Jan/24/2021	New Information

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-18-2021 06:54:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	eDiary: Stop Date 18-Jan-2021 for CHILLS in Inform is before the last eDiary date 24-Jan-2021. Please review and update as appropriate. Thanks
Feb-17-2021 15:02:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-17-2021 11:31:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per subject there were no ongoing symptoms after day 7
Feb-16-2021 03:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, Day 7 is the last day reported on 24-Jan-2021. However, in Inform for CHILLS stop



**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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

				date is provided as 18-Jan-2021. Please verify and consider to update as needed. Else, clarify. Thanks
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Jan/18/2021	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG	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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

			Were fever or s NO ystemic sympt oms present on the last day the Subject Diary was completed ?:	
--	--	--	---	--

**2.e Symptom:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: DI	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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

A  
RR  
HE  
AWere fever or s N  
ystemic sympto O  
ms present on t  
he last day the  
Subject Diary  
was completed  
?:**2.f Symptom:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

**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:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> <b>Symptom::</b> NEW OR W ORSE NED MUS CLE P AIN  <b>Were fever NO or systemic symptoms p resent on th e last day th e Subject Di ary was co mpleted?:</b>	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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**2.g Symptom:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED 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-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED JOIN T PAI N	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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Were fever NO or systemic symptoms p resent on th e last day th e Subject Di ary was com pleted?:</b>	
--	--	--	--	--

**2.h Symptom:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSEN ED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Feb-15-2021	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:3412:16:48  
(UTC-05:00)  
Eastern Time (US  
& Canada)

(autocalc)

DELTOID MUSCLE

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> R RE D N ES S <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**5.a Injection Site Reaction:**

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG  <b>Were injection</b> NO <b>site reactions p</b> <b>resent on the l</b> <b>ast day the Su</b> <b>bject Diary wa</b> <b>s completed?:</b>	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site PAI</b> <b>Reaction::</b> N A T IN JEC TIO N SI TE	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-15-2021 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-15-2021 12:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-15-2021 12:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-15-2021 13:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 12:17:31 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

**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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 12:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Feb/15/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-15-2021 13:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BTZPT : V	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 13:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BTZPTV	Initial Entry

**5.b**

**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:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-15-2021 13:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample I</b> BTZPT <b>D:</b> W	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 13:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BTZPTW	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-15-2021 13:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID</b> BKZ3C : 8	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 13:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b><u>Data Entry:</u></b> BKZ3C8	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-18-2021 11:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 05:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ : Details of Sample ID (barcode) and collection date for either Nasal Swab Self or Nasal Swab expected to be completed. Please check and update else clarify.
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-17-2021 13:40:58 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-17-2021 13:40:58 (UTC-05:00) Eastern 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.
Feb-17-2021 13:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/17/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 13:40:58 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)				
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/17/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/16/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Mar-04-2021 10:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Feb/19/2021	New Information
Feb-17-2021 13:42:32	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

**4.a**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEV ER <b>Symptom Pr NO</b> <b>esent:</b>	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt NEW OR I</b> <b>oms: NCREASE</b> <b>D COUGH</b>  <b>Sympt NO</b> <b>om Pre</b> <b>sent:</b>	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Feb-17-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

13:42:32  
(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4),  
(b) (6)

**Symptom:** NEW OR INCREASED SHORTNESS OF BREATH  
**Symptom Present:** NO

**4.c Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

LS

**Symptom Present:** YES**4.d Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symp</b> NEW OR IN <b>toms:</b> CREASED MUSCLE P AIN	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

			Symp NO tom P resent :	
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**4.e Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sympt NEW LOSS oms: OF TASTE OR SMELL	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Sympt NO om Pr esent:</b>	
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**4.f Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TAS TE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symp</b> NEW OR IN <b>toms:</b> CREASED SORE THR OAT	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

			Symp NO tom P resent :	
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**4.g Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms DIARR : HEA Symptom NO Present:	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**4.h Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> VOMI <b>:</b> TING <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**4.i Symptoms:**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Feb-17-2021 13:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-17-2021  
13:43:02  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

(b) (4),  
(b) (6)

**Data Entry:**  
Not Applicable

Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Feb-17-2021 13:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-17-2021 13:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-17-2021 13:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-18-2021 11:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 11:11:20 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-18-2021 11:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Feb/17/2021	New Information
Feb-17-2021 13:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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 11:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Feb-17-2021 13:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> subject to submit se If swab per protocol	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.a**

Date	Location	User	Value	Reason
Feb-18-2021 11:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> CV5527 <b>D:</b> 6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-18-2021 11:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CV55276	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-17-2021 13:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-17-2021 13:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-22-2021 10:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Feb-22-2021 10:56:47 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-22-2021 10:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Feb-22-2021 10:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Feb-22-2021 07:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-19-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-19-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-19-2021 06:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-18-2021 15:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-18-2021 14:58:02	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)				
Feb-18-2021 14:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/17/2021	New Information
Feb-18-2021 14:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Feb-17-2021 13:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-22-2021 10:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> telephone visit	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-18-2021 14:58:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Feb-17-2021 13:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> telephone visit	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-19-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> CV552 <b>D:</b> 76	Transcription Error (DELETED)
Feb-19-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> CV552 <b>D:</b> 76	New Information
Feb-18-2021 15:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> CV552 <b>D:</b> 76	Transcription Error (DELETED)
Feb-18-2021 14:57:30	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> CV552	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

**D:** 76

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CV55276	Transcription Error (DELETED)
Feb-19-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-19-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CV55276	New Information
Feb-19-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Feb-19-2021 00:04:06 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				
Feb-18-2021 15:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>CV55276</del>	Transcription Error <b>(DELETED)</b>
Feb-18-2021 14:59:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	wrong entry
Feb-18-2021 14:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Feb-18-2021 14:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CV55276	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021**Form Version:** 14-Jan-2021 02:24**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> SPEC <b>titioner:</b> IALI ST <b>Occurrence</b> NO <b>of Visits or</b> <b>Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:24**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34**1.b**

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pr</b> EMER <b>actioner:</b> GENC Y ROO M <b>Occurrence</b> NO <b>of Visits</b> <b>or Contact</b> <b>s:</b>	Initial Entry

**1.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROO M	Initial Entry

**1.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.c**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P PRIMAR</b> <b>ractition Y CARE</b> <b>er: PHYSICI</b> <b>AN</b> <b>Occurren NO</b> <b>ce of Visi</b> <b>ts or Con</b> <b>tacts:</b>	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE P HYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONTACT	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021**Form Version:** 14-Jan-2021 02:24**Site No:** 1131**Subject No:** 11311287**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34Eastern Time (US  
& Canada)**r:** NSULTA  
TION**Occurren NO  
ce of Visi  
ts or Con  
tacts:*****1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CON SULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practi OT tioner: HE R</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

**Occurrence of NO  
Visits or Cont  
acts:**

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Feb-17-2021 13:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/17/2021

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Feb-17-2021 13:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID- 19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Feb-17-2021 13:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-17-2021 13:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Category:**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-22-2021 12:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 11:07:13 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per site dr. ae symptoms are not related to

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				the covid-ill visit on feb/17/2021
Feb-19-2021 12:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	GPD Clin: Please update information per COVID ILLNESS VISIT 17-Feb. If symptoms are assessed as part of the COVID ILL symptoms, please move to COVID ILLNESS visit form.
Feb-17-2021 11:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> enlarge lymph nodes-neck(bilateral)	New Information
Feb-17-2021 11:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	dr. to clarify upon returned
Feb-15-2021 17:34:16 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Were enlarged lymph nodes

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				right, left, bilateral in neck? Please review and amend AE term as appropriate to indicate anatomic location.
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> enlarge lymph nodes-neck	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

Feb/3/2021 UNK:  
UNK

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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).***

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Category:**

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-25-2021 11:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-22-2021 11:07:43	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per site dr. ae symptoms are



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		not related to the covid-ill visit on feb/17/2021
Feb-19-2021 19:14:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued: Opened	Clin: Since RUNNY NOSE is one of the CDC-defined symptoms of COVID-19 (Prot Sect 8.1), please consider whether this symptom, could have been due to COVID-19 and should have triggered a potential COVID illness visit
Feb-17-2021 11:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	yes subject is having covid illness visit today
Feb-16-2021 10:37:59 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Since RUNNY NOSE is one of the

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)				CDC-defined symptoms of COVID-19 (Prot Sect 8.1), please consider whether this symptom, could have been due to COVID-19 and should have triggered a potential COVID illness visit
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> rhinorrhea	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/17/2021 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/3/2021 UNK: UNK	Initial Entry
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**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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).***

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*9. Is this event related to study treatment:*

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to st udy treatment(s), thi s event is due to:  OTHER  <i>If Other, specify:</i>  unknown viral exposure	Initial Entry

*10. Latest Action Taken with Study Treatment:*

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:12:02	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)

Eastern Time (US  
& Canada)

(b) (4), (b) (6)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-25-2021 06:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Closed	Response satisfies query
Feb-24-2021 12:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Answered	data erased and all forms mark not applicable except the form with the date that i could not erase
Feb-24-2021 03:47:25 (UTC-05:00) Eastern 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

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

				data from rest of forms and mark the forms as Not Done/Not Applicable at form level comment or else clarify.
Feb-23-2021 16:53:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Visit is erroneous
Feb-23-2021 11:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: 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.



**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-23-2021 11:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 11:47:02 (UTC-05:00) Eastern 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-15-2021 12:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/15/2021	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-23-2021 11:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> ERRONEOUS VIS IT	Initial Entry
Feb-23-2021 11:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b>	Transcription Error
Feb-23-2021 11:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> ERRONEOUS VIS IT	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form Version:** 14-Jan-2021 02:29

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Consent Was:**

Date	Location	User	Value	Reason
Feb-24-2021 12:16:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-23-2021 11:47:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-15-2021 12:32:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Con sent Obtained  Feb/15/2021	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-23-2021 11:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-15-2021 12:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-23-2021	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Transcription

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

11:49:08 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)		Error
Feb-15-2021 12:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-23-2021 11:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Transcription Error
Feb-15-2021 12:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-24-2021 12:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-24-2021 12:16:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-15-2021 12:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> sample collected on the same day at visi t 3	Initial Entry

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311287

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-24-2021 12:17:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-23-2021 11:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-15-2021 12:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-24-2021 12:17:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-23-2021	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Transcription

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

11:48:44 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)		Error
Feb-15-2021 12:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-24-2021 12:17:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-23-2021 11:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Answer Auto Query
Feb-23-2021 11:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-22-2021 14:56:22 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	DM: Following up with Triad/CRA to



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				help resolve
Feb-22-2021 14:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 11:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	this was an erroneous entry visit 201 did not take place
Feb-22-2021 11:14:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-22-2021 11:14:39 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
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**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				
Feb-22-2021 11:14:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	this visit 201 did not take place it was an erroneous entry
Feb-19-2021 17:20:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Query response is 'data updated'; however, barcode is still missing on this form. Please add the barcode under 'Sample ID' below. If nasal swab was not collected, please update 'Sample Collected' to 'No'.
Feb-19-2021 10:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated
Feb-19-2021 01:07:04	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Sample collected is yes

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)				hence Barcode details needs to be updated. Please update barcode details else mark No or else clarify. Thank you.
Feb-18-2021 15:01:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data is now updated it was entered in a wrong location
Feb-18-2021 14:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM RQ1: Response is 'data updated' however barcodes are still missing. Please enter nasal swab barcode for V4 or change to 'Sample Collected?' = No. Please review and update as appropriate.
Feb-18-2021 11:12:53 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				
Feb-17-2021 07:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 12:33:49 (UTC-05:00) Eastern 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-15-2021 12:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/15/2021	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-24-2021 12:17:24 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				
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090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-15-2021 12:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/15/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-15-2021 12:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-15-2021 12:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3006\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311287**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Feb-15-2021 12:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-29-2020 14:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDO MIZED	Initial Entry
Dec-29-2020 14:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Feb-15-2021 12:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/15/2021	Initial Entry
Dec-29-2020 14:59:48	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311287

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)				
Dec-29-2020 14:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b><u>Data Entry:</u></b> Dec/29/2020	Initial Entry