

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, 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 Aug/27/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11311095]
2.	Birth Date:	(b) (6)/1960
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, 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

	Date of Visit		Comments
1.	Date of Visit	Sep/9/2020	
2.	Erroneous Visit		

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, 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	Sep/9/2020
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: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, 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:	[dizziness, related to travel by boat]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[myopia]
	Start Date:	UNK/UNK/1966
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[eye glass wearer]
	Start Date:	UNK/UNK/1966
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[contact wearer]
	Start Date:	UNK/UNK/1966
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cataracts in both eyes, mild]
	Start Date:	May/UNK/2020
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergic rhinitis, seasonal]
	Start Date:	UNK/UNK/1972
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[elevated cholesterol, specific level unknown]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gallstones]
	Start Date:	UNK/UNK/2006
	Ongoing:	NO End Date: UNK/UNK/2006
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[migraine headaches]
	Start Date:	UNK/UNK/1979
	Ongoing:	YES

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypothyroidism]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[lower back pain, undiagnosed etiology]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteopenia]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[vitamin D deficiency]
	Start Date:	Apr/UNK/2020
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hashimoto disease]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hysterectomy]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cholecystectomy]
	Start Date:	UNK/UNK/2006
	Ongoing:	NO End Date: UNK/UNK/2006

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, 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:	Sep/9/2020
2.	Weight:	[73.6]
3.	Unit:	kg
4.	Height:	[168.5]
5.	Unit:	cm
6.	Body Mass Index:	[25.9]

Vital Signs Details

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, 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:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Done _____ //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, 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 :	Sep/9/2020
2.	Randomization Number:	[255945]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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: Sep/9/2020
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	[BL9W13]
5.b	Sample ID	[BL9W14]
5.c	Sample ID	[BP99P2]

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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: Sep/9/2020
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	[BN6DZX]
-----	-----------	----------

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Aug/27/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/9/2020 14:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, 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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, 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	Sep/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, 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:	Sep/29/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, 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:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Done _____ //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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: Sep/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	[BP9B2R]
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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:	Sep/29/2020 15:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, 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	Oct/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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: Oct/28/2020
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	[BS7X8P]
5.b	Sample ID	[BS7X8M]
5.c	Sample ID	[BP99Y9]

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Dec/15/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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/15/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/15/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/15/2020
2.	Date of First Symptom Started:	Dec/14/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/12/2021

Symptoms

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Dec/15/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

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

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: 11311095

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 Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

Microbiology Specimen

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/15/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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: Dec/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[patient to bring swab into office]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV00808]
-----	-----------	-----------

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB on Dec/15/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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:	[patient was instructed to self swab and bring to the site]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Dec/15/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311095**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
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Dec/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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

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: 11311095

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Dec/15/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Dec/15/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

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

Lab Result

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/15/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/15/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/15/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

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

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

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

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

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Subject Initials: ---

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 11311095

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.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Dec/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Oxygenation Parameters

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

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: 11311095

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Dec/15/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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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: 11311095

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Jan/12/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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/12/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Jan/12/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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: Jan/12/2021
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	[BS7XRF]
5.b	Sample ID	[BS7XRD]
5.c	Sample ID	[BR0F7D]

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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 :	Oct/28/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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: 11311095

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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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 11311095

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	malaise	Sep/30/2020 UNK:UNK	NO End Date Time: Oct/1/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	swollen axillary lymph nodes	Sep/30/2020 UNK:UNK	NO End Date Time: Oct/2/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	headache	Sep/30/2020 07:00	NO End Date Time: Oct/2/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	generalized myalgia	Oct/2/2020 02:00	NO End Date Time: Oct/2/2020 08:00	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[malaise]
4.	Start Date Time:	Sep/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/1/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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

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 - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[swollen axillary lymph nodes]
4.	Start Date Time:	Sep/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/2/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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

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 - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Sep/30/2020 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/2/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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 - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[generalized myalgia]
4.	Start Date Time:	Oct/2/2020 02:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/2/2020 08:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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: 11311095

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1131

Subject No: 11311095

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	[]

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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: 11311095

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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:	//

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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: 11311095

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

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?	

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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: 11311095

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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

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: 11311095

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: 11311095

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: 11311095

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:	

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

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: 11311095

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?	

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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: 11311095

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: Potential ReVax Initial Contact -
Unscheduled

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: 11311095

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/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT

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	Dec/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

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 - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/23/2020
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Dec/23/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1131

Subject No: 11311095

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:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/23/2020
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	[BR0F57]
5.b	Sample ID	[BS7XN0]
5.c	Sample ID	[BS7XN1]

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/23/2020
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	[BP9B86]
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/23/2020 08:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/22/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

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: 11311095

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: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT

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	Jan/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1131

Subject No: 11311095

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:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
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	[BP9B9F]
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/12/2021 11:29
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT

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/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: CONTACT OUTCOME

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](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/9/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
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: 11311095

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/9/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/28/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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 Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-19-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Aug-31-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Delayed vaccine per physician due to muscle pain in neck for several days. No vaccine administered on the initial screening day so not considered the "visit date" per CRF guidelines. <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-09-2020 19:12:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	no inclusion or exclusion criteria met
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-10-2020 08:54:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	subject not of childbearing age <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-29-2020 15:45:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject not of childbearing potential
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
6	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
7	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
8	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
9	Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

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Subject No: 11311095

Subject Initials: ---

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Item	Date	User	Comment
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1	Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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2	Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
2	Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

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3	Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable
3	Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

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4	Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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6	Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
6	Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Dec/15/2020

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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Item	Date	User	Comment
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Header Text: c4591001

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Form Status: Data Complete, Frozen

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Item	Date	User	Comment
5.b	Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

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Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5 h	Dec-16-2020 08:33:02 (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 Dec/15/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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Generated By: (b) (4)

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

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Item	Date	User	Comment
5 h	Dec-16-2020 08:33:02 (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 Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

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

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Item	Date	User	Comment
5 h	Dec-16-2020 08:33:02 (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 Dec/15/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

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Site No: 1131

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Item	Date	User	Comment
5.i	Dec-16-2020 08:33:02 (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 Dec/15/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

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

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Item	Date	User	Comment
5.i	Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

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Item	Date	User	Comment
5.i	Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

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Item	Date	User	Comment
5.i	Dec-16-2020 08:33:02 (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 Dec/15/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Dec-16-2020 08:33:02 (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 Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

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Item	Date	User	Comment
5.j	Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Item	Date	User	Comment
5.j	Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

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Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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

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Item	Date	User	Comment
5.j	Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.a	Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
2.a	Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

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Item	Date	User	Comment
2.a	Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
2.a	Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-16-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Dec-16-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Dec/15/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.a	Dec-16-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-16-2020 08:34:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Dec-16-2020 08:34:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Dec-16-2020 08:34:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
3	Dec-16-2020 08:34:11 (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 Dec/15/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-16-2020 08:34:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Dec-16-2020 08:34:45 (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 Dec/15/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Dec-16-2020 08:34:45 (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 Dec/15/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

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Item	Date	User	Comment
3	Dec-16-2020 08:34:45 (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 Dec/15/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
4	Dec-16-2020 08:34:45 (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 Dec/15/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Dec-16-2020 08:34:45 (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 Dec/15/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Dec-16-2020 08:34:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

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Subject No: 11311095

Subject Initials: ---

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

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Item	Date	User	Comment
2	Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:53

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

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Item	Date	User	Comment
3	Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

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Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
4	Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-30-2020 09:05:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
3	Dec-30-2020 09:31:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
3	Jan-12-2021 14:34:39 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is 60 years old
			Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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
(b) (6)	N/A	Feb-09-2021 13:06:46 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

William Randall	Approved	Jan-22-2021 12:31:35 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	---	------	--------

Affidavit:

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

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

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

(b) (6)	N/A	Nov-24-2020 13:12:24 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

William Randall	Approved	Nov-03-2020 09:07:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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 - Protocol version

Date	Location	User	Value	Reason
Aug-31-2020 12:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-23-2020 00:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 09:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-22-2020 07:36:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Vaccination CRF is unfrozen, please consider updating as appropriate. Thank you.
Oct-20-2020 09:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vaccination CRF Data is frozen; if unfrozen, the EDC will be updated.
Oct-20-2020 08:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: As per VACCINATION CRF at V1_DAY1_VAX1_L, there is no temporary delay of vaccination recorded. Please consider to update VACCINATION CRF if appropriate. Thanks
Oct-19-2020 11:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct as is- informed consent obtained on 27AUG2020 and due to delay of vaccine because of muscle pain in neck, visit 1 finished on 09SEP2020.
Oct-19-2020 11:04:05 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Time (US & Canada)				not the same as the Date of Visit. Please correct as necessary.
Aug-31-2020 12:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/27/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Aug-31-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11311095	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-31-2020 12:23:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1960	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-31-2020 12:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-31-2020 12:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A)) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 12:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-23-2020 00:20:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 09:05:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-22-2020 07:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Vaccination CRF is unfrozen, please consider updating as appropriate. Thank you.
Oct-20-2020 09:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vaccination CRF Data is frozen; if unfrozen, the EDC will be updated.
Oct-20-2020 08:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: As per VACCINATION CRF at V1_DAY1_VAX1_L, there is no temporary delay of vaccination recorded. Please consider to update VACCINATION CRF if appropriate. Thanks
Oct-19-2020 11:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Delayed vaccine per physician due to muscle pain in neck for several days. No vaccine administered on the initial screening day so not considered the "visit date" per CRF guidelines. Vaccine administered on 9SEP

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

				so EDC is updated.
Oct-19-2020 11:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sep/9/2020	Delayed vaccine per physician due to muscle pain in neck for several days. No vaccine administered on the initial screening day so not considered the "visit date" per CRF guidelines. Vaccine administered on 9SEP so EDC is updated.
Oct-19-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Initial Entry
Oct-18-2020 02:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Subject received vaccination on 09Sep2020, but Date of visit is marked as NOT DONE. Please verify and update the date. Else clarify.
Aug-31-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Sep-10-2020 16:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Delay of vaccine administration and the screening visit was completed 9SEP2020.
Aug-31-2020 12:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-31-2020 12:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-11-2020 02:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Per site confirmation
Sep-10-2020 08:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Sep-10-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Response to "Status" is COMPLETED but "Specify Status" is Provided.
Sep-10-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Sep-10-2020 08:35:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	New Information

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Time (US & Canada)				
Sep-10-2020 01:42:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: The page is unfreeze. Per response please consider to update the data as appropriate.
Sep-09-2020 19:14:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	page is frozen.page needs to be unfrozen for me to be able to update the subjects status and enter visit info, including barcodes
Sep-09-2020 02:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM2: Thank you for confirming. Please respond to query only once updates are made.
Sep-08-2020 10:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Still waiting on CRA Dominic Mainello's guidance for delay vaccine EDC. Will query again- Thank you for your patience.
Sep-07-2020 08:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM Requery: Thanks for your response. Once guidance receive from the CRA, Kindly update the screening disposition status.
Sep-03-2020 09:13:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Thank you for your patience, this subject had a delay in vaccine administration and didn't get randomized or complete Visit 1.

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1131**Subject No:** 11311095**Generated By:** (b) (4)**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

				We are seeking guidance from CRA how to best categorize the screening disposition. It wasn't completed or a screen failure.
Sep-03-2020 08:44:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	SDQ: As per Impala, Subject status is Screening. Please review and update as appropriate. Thank you.
Aug-31-2020 12:31:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-31-2020 12:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is OTHER but "Specify Status" is missing.
Aug-31-2020 12:31:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-31-2020 12:31:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: OTHER	Changed Information
Aug-31-2020 12:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is PHYSICIAN DECISION but "Specify Status" is Provided.
Aug-31-2020 12:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: PHYSICIAN DECISION	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Sep-10-2020 08:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Aug-31-2020 12:31:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Delayed vaccine per physician d ue to muscle pain in neck for se veral days.	Initial Entry
Aug-31-2020 12:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-31-2020 12:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Delayed vaccine per physician d ue to muscle pain in neck for se veral days.	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Sep-10-2020 08:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: dizziness, related to travel by boat Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: dizziness, related to travel by boat	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

I.b

Date	Location	User	Value	Reason
Sep-10-2020 08:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: myopia Start Date: UNK/UNK/ 966 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: myopia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1966	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-10-2020 08:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History T eye glass wea erm: rer Start Date: UNK/UNK/1 966 Ongoing: YES	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: eye glass wearer	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1966	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Sep-10-2020 08:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 4 : Medical History T contact weare erm: r Start Date: UNK/UNK/1 966 Ongoing: YES	Initial Entry
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1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: contact wearer	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1966	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-10-2020 08:39:27 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 5	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Time (US & Canada)			ber: Medical Histor y Term: cataracts in both eyes, mild Start Date: May/UNK/2020 Ongoing: YES
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cataracts in both eyes, mild	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> May/UNK/2020	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-10-2020 08:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Num 6 ber: Medical Histor y Term: allergic rhinitis, seasonal	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

			Start Date: UNK/UNK/1972	
			Ongoing: YES	

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: allergic rhinitis, seasonal	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1972	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-10-2020 08:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 7 umber: Medical Hi elevated cholesterol, story Term specific level unkno : wn Start Date: UNK/UNK/2015	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Subject No: 11311095

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Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

			Ongoing: YES	
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I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: elevated cholesterol, specific level unknown	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-10-2020 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: gallstones Start Date: UNK/UNK/2006	Initial Entry

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Header Text: c4591001

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Subject No: 11311095

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

			Ongoing:	NO End Date: UNK/UNK/ 2006
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1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: gallstones	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2006	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2006	Initial Entry

1.i

Date	Location	User	Value	Reason
Sep-10-2020 08:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9	Initial Entry

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Header Text: c4591001

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Subject No: 11311095

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

			Medical History Term: migraine head aches Start Date: UNK/UNK/1979 Ongoing: YES	
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1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: migraine headaches	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1979	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-10-2020 08:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 10 : Medical History Term: hypothyroidism	Initial Entry

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Header Text: c4591001

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Subject No: 11311095

Generated By: (b) (4)

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Subject Initials: ---

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

			Start Date:	UNK/UNK/1989	
			Ongoing:	YES	

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypothyroidism	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11311095

Generated By: (b) (4)

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<i>I.k</i>				
Date	Location	User	Value	Reason
Sep-10-2020 08:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 11 umber: Medical His lower back pain, un tory Term: diagnosed etiology Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

<i>I.k Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 08:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

<i>I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 08:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lower back pain, undiagnosed eti ology	Initial Entry

<i>I.k Start Date:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 08:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

<i>I.k Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-10-2020 08:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

<i>I.l</i>				
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Header Text: c4591001

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Date	Location	User	Value	Reason
Sep-10-2020 08:42:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 12 : Medical History Term: osteopenia Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:42:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-10-2020 08:42:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: osteopenia	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:42:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:42:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
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Header Text: c4591001

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Generated By: (b) (4)

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Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Sep-10-2020 08:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term: vitamin D deficiency Start Date: Apr/UNK/2020 Ongoing: YES	Initial Entry
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1.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vitamin D deficiency	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2020	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.n

Date	Location	User	Value	Reason
Sep-10-2020 08:44:08 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

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Header Text: c4591001

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Time (US & Canada)			Line/MH Number: 14	
			Medical History Term: Hashimoto disease	
			Start Date: UNK/UNK/1989	
			Ongoing: YES	

I.n Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hashimoto disease	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.o

Date	Location	User	Value	Reason
Sep-10-2020 08:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 15	Initial Entry

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Header Text: c4591001

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Subject No: 11311095

Generated By: (b) (4)

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Subject Initials: ---

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			:	
				Medical History Term: hysterectomy
			Start Date:	UNK/UNK/2003
			Ongoing:	YES

I.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hysterectomy	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2003	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 08:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.p

Date	Location	User	Value	Reason
Sep-11-2020 15:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 16	Transcription Error

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			Medical History Term: cholecystectomy Start Date: UNK/UNK/2006 Ongoing: NO End Date: UNK/UNK/2006	
Sep-10-2020 08:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: cholecystectomy Start Date: UNK/UNK/2006 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11311095

Generated By: (b) (4)

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Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

1.p Line/MH Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cholecystectomy	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2006	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Sep-13-2020 12:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-11-2020 15:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-11-2020 15:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2006	Transcription Error
Sep-11-2020 15:22:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - CHOLECYSTECTOMY is reported as Ongoing. However, as a surgical procedure, it is expected to have the same start

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Generated By: (b) (4)

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				and end dates. Please review and update as appropriate.
Sep-10-2020 08:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 73.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 168.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.9	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Temperature: 37.0 Temperature Unit C : Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-10-2020 08:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 08:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defi 113 ned Identifier : Test:: Choriogonadotr opin Beta_PX11 3 Result:: Not Done:: NOT DONE	Initial Entry
Sep-10-2020 08:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi ned Identifier : Test:: Choriogonadotr opin Beta_PX11 3 Result:: Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 08:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-10-2020 08:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX11 3	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-10-2020 08:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Sep-10-2020 08:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-10-2020 08:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 255945	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Sep-10-2020 08:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 08:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 08:57:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 08:55:18 (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.
Sep-10-2020 08:55:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 08:57:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9W13	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 08:57:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9W13	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-10-2020 08:57:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9W14	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 08:57:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9W14	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-10-2020 08:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP99P2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 08:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP99P2	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Sep-10-2020 08:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 08:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 08:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 08:55:26 (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.
Sep-10-2020 08:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 08:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6DZX	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 08:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6DZX	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Oct-22-2020 09:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Aug/27/2020 Reason(s) for Temporary Dela y of Vaccination FEVER OR ACUTE ILLNE SS	Acute condition- muscle pain in neck
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 14:33	Initial Entry

5. Anatomical Location:

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Sep-10-2020 08:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Sep-29-2020 15:08:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-29-2020 15:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Temperature: 36.6 Temperature Unit C : Temperature Loc ORAL CAV ation: ITY	Initial Entry
Sep-29-2020 15:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: Temperature Unit: Temperature Location:	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 15:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-29-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

2.a Unit:

Date	Location	User	Value	Reason
Sep-29-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-29-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 15:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-29-2020 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defi 113 ned Identifier : Test:: Choriogonadotr opin Beta_PX11 3 Result:: Not Done:: NOT DONE	Initial Entry
Sep-29-2020 15:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi ned Identifier : Test:: Choriogonadotr opin Beta_PX11 3 Result:: Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-29-2020 15:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX11 3	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Sep-29-2020 15:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 15:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 15:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 15:08:57 (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.
Sep-29-2020 15:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 15:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP9B2R	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP9B2R	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Sep-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020 15:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 15:46:32 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Time (US & Canada)

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

7. Route:

Date	Location	User	Value	Reason
Sep-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Oct-28-2020 15:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Oct-28-2020 15:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-28-2020 15:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-28-2020 16:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 15:23:27 (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.
Oct-28-2020 15:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-28-2020 16:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS7X8P	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 16:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS7X8P	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-28-2020 16:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS7X8M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 16:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS7X8M	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-28-2020 16:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP99Y9	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 16:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP99Y9	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/15/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-16-2020 23:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-16-2020 08:36:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Subject was instructed to bring in self swab. We are still waiting for that
Dec-16-2020 01:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	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.
Dec-15-2020 13:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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.
Dec-15-2020 13:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-15-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/15/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

				the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-15-2020 13:35:39 (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.
Dec-15-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/15/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-15-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/15/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/14/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-14-2021 12:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-13-2021 11:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-13-2021 11:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/12/2021	New Information
Jan-13-2021 09:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' to 'NO' and add Date of

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

				Last Symptom Resolved on the CRF.
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREA : SED COUGH Symptom NO Present:	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311095**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSC LE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

4.f

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311095**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**4.g Symptoms:**

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Present NO :	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present NO :	Initial Entry
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4.i Symptoms:

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 13:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-15-2020 13:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: laryngitis	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-15-2020 13:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: laryngitis	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry
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7. Test Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-16-2020 08:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311095**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
Dec-15-2020 13:57:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-15-2020 13:57:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-16-2020 15:05:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-16-2020 15:05:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/16/2020	New Information
Dec-16-2020 15:04:12 (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.
Dec-15-2020 13:57:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Dec-15-2020 13:57:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: patient to bring swab into office	Initial Entry
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5.a

Date	Location	User	Value	Reason
Dec-16-2020 15:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV00808	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 15:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV00808	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

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: 11311095

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
Dec-15-2020 13:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-15-2020 13:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-15-2020 13:55:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-15-2020 13:54:12 (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.
Dec-15-2020 13:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-15-2020 13:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Transcription Error

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Dec-15-2020 13:47:46 (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.
Dec-15-2020 13:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/15/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Dec-15-2020 13:55:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: patient was instructed to self swa b and bring to the site	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/15/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/15/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/15/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/15/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATIO N	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

I.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

I.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/15/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Dec-15-2020 13:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-16-2020 08:31:27	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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 Done	
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5. Start Date:

Date	Location	User	Value	Reason
Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Dec-16-2020 08:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-16-2020 08:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Dec/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Dec-16-2020 08:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Dec/15/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Dec-16-2020 08:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	Not Applicable
			Lab Normal Range :	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range : Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

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Form Version: 21-Aug-2020 02:49

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Site No: 1131

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Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject No: 11311095

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Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:	able	

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:	Not Applicable	

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:	Not Applicable	

Header Text: c4591001

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Subject No: 11311095

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

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Date	Location	User	Value	Reason
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5.e Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

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Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

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Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	Not Applicable
			Lab Normal Range :	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

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Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range : Not Applicable	Initial Entry

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Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applic	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:	able	

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Dec-16-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in r Not App espirations/minute: licable Heart Rate in beats/m Not App inute: licable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Dec/15/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-16-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier Not Applicable : Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-16-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Dec-16-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Dec/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Dec-16-2020 08:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Dec-16-2020 08:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Dec-16-2020 08:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/15/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Dec-16-2020 08:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-16-2020 08:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-16-2020 08:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Dec-16-2020 08:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Dec-16-2020 08:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/15/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

6. Ongoing?

Date	Location	User	Value	Reason
Dec-16-2020 08:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History on Dec/15/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Dec-16-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Jan/12/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Jan-12-2021 14:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-12-2021 14:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/12/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1131**Subject No:** 11311095**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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-12-2021 14:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 14:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 17:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-12-2021 14:30:05 (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.
Jan-12-2021 14:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 17:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS7XRF	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/12/2021

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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 17:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS7XRF	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-12-2021 17:19:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS7XRD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 17:19:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS7XRD	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-12-2021 17:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0F7D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 17:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR0F7D	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Oct-28-2020 15:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-28-2020 15:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-28-2020 15:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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:

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: malaise	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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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
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 15:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-24-2020 13:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-24-2020 13:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Nov-24-2020 12:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Malaise is reported to have Recovered/Resolved with SEQUELAE. Please review if this selection is correct for this event; clarify sequelae in query response
Oct-15-2020 15:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED W ITH SEQUELAE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:23:44	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

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

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

NO

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: 11311095

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
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: swollen axillary lymph nodes	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/2/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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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
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 07:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/2/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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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
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: generalized myalgia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020 02:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/2/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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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
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Dec-23-2020 12:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1131**Subject No:** 11311095**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - 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. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Dec-23-2020 12:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-23-2020 12:24:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-23-2020 12:24:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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-23-2020 12:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER 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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I. Consent Was:

Date	Location	User	Value	Reason
Dec-23-2020 12:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/23/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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-18-2021 14:51:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Closed	Response satisfies query
Feb-18-2021 10:52:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-18-2021 10:52:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Transcription Error
Feb-18-2021 01:41:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Date is reported as 29Dec2020, but subject received vaccination on 23Dec2020. Please confirm the date is correct as entered or update if necessary. Otherwise clarify. Thank you.
Dec-30-2020 09:06:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-30-2020 09:06:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-30-2020 09:06:05 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)

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

Header Text: c4591001**Visit:** V101_VAX3**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:** 11311095**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-30-2020 09:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Dec-30-2020 09:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier : Test:: Choriogonadotropin Beta_PX113 Result:: Not Done::	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-30-2020 09:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

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
Dec-30-2020 09:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 09:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 09:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 09:21:28 (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.
Dec-30-2020 09:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-30-2020 09:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0F57	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 09:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BR0F57	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-30-2020 09:22:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID: BS7XN0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 09:22:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BS7XN0	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-30-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID: BS7XN1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 09:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BS7XN1	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311095**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
Dec-30-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 09:23:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 09:22:57 (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.
Dec-30-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Dec/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-30-2020 09:23:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BP9B86	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 09:23:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BP9B86	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1131

Subject No: 11311095

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-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020 08:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1131

Subject No: 11311095

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

Time (US & Canada)	(b) (4), (b) (6)
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7. Route:

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 09:32:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-23-2020 12:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-23-2020 12:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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-12-2021 14:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

Header Text: c4591001**Visit:** V102_VAX4**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:** 11311095**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-12-2021 14:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-12-2021 14:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier 113 : Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
Jan-12-2021 14:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier : Test:: Choriogonadotropin Beta_PX113 Result:: Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-12-2021 14:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Header Text: c4591001

Visit: V102_VAX4

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: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-12-2021 14:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-12-2021 14:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311095**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
Jan-12-2021 14:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 14:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 17:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-12-2021 14:35:39 (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.
Jan-12-2021 14:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 17:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP9B9F	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 17:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP9B9F	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1131

Subject No: 11311095

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-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021 11:29	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1131

Subject No: 11311095

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

Time (US & Canada)	(b) (4), (b) (6)
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7. Route:

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 14:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311095

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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I. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 07:42:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per data updated by site.
Feb-10-2021 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated
Feb-10-2021 07:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103.
Feb-09-2021 13:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: CONTACT OUTCOME - 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. Contact Type:

Date	Location	User	Value	Reason
Feb-09-2021 13:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-09-2021 13:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/9/2021	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
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:** 11311095**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-11-2021 08:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Clo sed	Incorrect Query
Feb-10-2021 16:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 1: Op ened	DMW7223661;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-10-2021 10:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : Feb/9/ 2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-10-2021 10:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-10-2021 10:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311095

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-28-2020 15:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-31-2020 12:31:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREEN FAIL	Changed Information
Aug-31-2020 12:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREEN FAIL	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-28-2020 15:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/28/2020	Initial Entry
Aug-31-2020 12:31:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Changed Information
Aug-31-2020 12:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry

090177e196ae3eac\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311095

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-16-2020 10:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry