

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: COHORT_SELECTION

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](#)

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: 11311145

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 Sep/8/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11311145]
2.	Birth Date:	(b) (6)/1944
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1131

Subject No: 11311145

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 _____
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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: 11311145

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/8/2020
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: 11311145

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:	[decreased hearing in both ears]	
	Start Date:	UNK/UNK/2019	
	Ongoing:	YES	
1.b	Line/MH Number:	[2]	Comments
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[dizziness]	Comments
	Start Date:	Jan/UNK/2020	Comments
	Ongoing:	NO End Date: Aug/UNK/2020	Comments
1.c	Line/MH Number:	[3]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[full denture wearer]	
	Start Date:	UNK/UNK/2015	
	Ongoing:	YES	
1.d	Line/MH Number:	[4]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[eye glass wearer]	
	Start Date:	UNK/UNK/1949	
	Ongoing:	YES	
1.e	Line/MH Number:	[5]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral cataracts]	
	Start Date:	UNK/UNK/2018	
	Ongoing:	NO End Date: Mar/UNK/2020	

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cataract surgery in both eyes]
	Start Date:	Mar/UNK/2020
	Ongoing:	NO End Date: Mar/UNK/2020
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic obstructive pulmonary disease, severe]
	Start Date:	Jan/UNK/2019
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[atrial fibrillation]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[edema in both legs]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[elevated cholesterol, specific level unknown]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[coronary artery disease]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[heart failure with reserved ejection fraction]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[urinary incontinence, urge]
	Start Date:	Aug/UNK/2019
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[benign prostatic hyperplasia]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetic neuropathy of feet, bilaterally]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[peripheral neuropathy of feet, bilaterally]
	Start Date:	Apr/UNK/2019
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetes type II without any history of ketoacidosis]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteoporosis]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[eczema, bilaterally in arms and legs]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[insomnia]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[edema in ankles]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[transurethral resection of prostate]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[high blood pressure]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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 x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic kidney disease, stage 3]
	Start Date:	Oct/UNK/2019
	Ongoing:	YES

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1131

Subject No: 11311145

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/8/2020
2.	Weight:	[92.0]
3.	Unit:	kg
4.	Height:	[186.2]
5.	Unit:	cm
6.	Body Mass Index:	[26.5]

Vital Signs Details

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

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1131
Subject No: 11311145
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/8/2020
2.	Randomization Number:	[252464]
3.	Randomization Group:	[]

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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/8/2020
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	[BN6DS5]
5.b	Sample ID	[BL9W09]
5.c	Sample ID	[BL9W0B]

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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/8/2020
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	[BN6DZ4]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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/8/2020 13:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1131

Subject No: 11311145

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
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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

			Comments
1.	Date of Visit	Not Applicable _____ //	
2.	Erroneous Visit		

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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

Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Temperature:	Not Applicable _____ []	Comments
	Unit:	Not Applicable _____	Comments
	Temperature Location:	Not Applicable _____	Comments

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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

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

Vaccination

1.	Was there a temporary delay of vaccination?	Not Applicable _____	Comments
2.	Treatment Name	Not Applicable _____ []	Comments
3.	Formulation:	Not Applicable _____	Comments
4.	Dose Date Time:	Not Applicable _____ //	Comments
5.	Anatomical Location:	Not Applicable _____	Comments
6.	Body Side:	Not Applicable _____	Comments
7.	Route:	Not Applicable _____	Comments
8.	Actual Dose:	Not Applicable _____ []	Comments
9.	Unit:	Not Applicable _____	Comments
10.	Timeframe Subject Was Observed	Not Applicable _____	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Applicable _____	Comments

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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: 11311145

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: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: 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: 11311145

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		Form: UNPLANNED VISIT
Visit: Unplanned - New Unscheduled Visit		Form Status: Not Started
Form Version: 22-Apr-2020 21:04		Site Name: (1131) PriMED Clinical Research
Site No: 1131		Subject Initials: ---
Subject No: 11311145		Generated Time (GMT): 29-Mar-2021 11:34
Generated By: (b) (4)		
Unplanned Assessments		
1.	Assessments	

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

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Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Dec/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	LOST TO FOLLOW-UP
4.	Specify Status:	[Subject has not reached out to site after repeated attempts. Certified letter delivered 07DEC2020]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

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 - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Dec/7/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	LOST TO FOLLOW-UP
4.	Specify Status:	[Subject has not reached out to site after repeated attempts. Certified letter delivered 07DEC2020]

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: 11311145

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:	
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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: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

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	Frequent falls	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	abrasion of right forearm	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	tingling of bilateral limbs, intermittent	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages
4.	ADVERSE EVENT	4	generalized weakness, intermittent	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages
5.	ADVERSE EVENT	5	Syncope	Oct/8/2020 UNK:UNK	NO End Date Time: Oct/13/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Hypotension, orthostatic	Oct/18/2020 UNK:UNK	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	hypovolemia	Oct/8/2020 UNK:UNK	NO End Date Time: Oct/13/2020 UNK:UNK	Repeating Pages
8.	ADVERSE EVENT	8	Atrial fibrillation with rapid ventricular response	Oct/8/2020 UNK:UNK	NO End Date Time: Oct/13/2020 UNK:UNK	Repeating Pages
9.	ADVERSE EVENT	9	hypovolemia	Oct/18/2020 UNK:UNK	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages
10.	ADVERSE EVENT	10	diabetic foot ulcer, right foot	Oct/18/2020 UNK:UNK	YES	Repeating Pages
11.	ADVERSE EVENT	11	acute kidney injury	Oct/8/2020 UNK:UNK	NO End Date Time:	Repeating Pages

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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: 11311145

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
					Oct/13/2020 UNK:UNK	
12.	ADVERSE EVENT	12	acute kidney injury	Oct/18/2020 UNK:UNK	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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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)	[Frequent falls]	
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
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:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	Comments
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]	

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Header Text: c4591001

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Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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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)	[abrasion of right forearm]
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

[Comments](#)

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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15.	Serious Adverse Event Number: For Pfizer Use Only	[]	
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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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)	[tingling of bilateral limbs, intermittent]
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

[Comments](#)

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

15.	Serious Adverse Event Number: For Pfizer Use Only	[]	
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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 weakness, intermittent]
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Syncope]
4.	Start Date Time:	Oct/8/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/13/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Hypovolemia]
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: 11311145

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?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020411549]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hypotension, orthostatic]
4.	Start Date Time:	Oct/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Hypovolemia due to poor oral intake]
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: 11311145

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?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020411512]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[hypovolemia]
4.	Start Date Time:	Oct/8/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/13/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [due to poor intake]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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

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: 11311145

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:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Atrial fibrillation with rapid ventricular response]
4.	Start Date Time:	Oct/8/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/13/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Hypovolemia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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

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: 11311145

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:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[hypovolemia]
4.	Start Date Time:	Oct/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Inadequate intake]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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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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: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[10]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[diabetic foot ulcer, right foot]
4.	Start Date Time:	Oct/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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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: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[11]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[acute kidney injury]
4.	Start Date Time:	Oct/8/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/13/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hypovolemia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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Header Text: c4591001

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Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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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: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[12]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[acute kidney injury]
4.	Start Date Time:	Oct/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hypovolemia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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

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: 11311145

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

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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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: 11311145

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

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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.	Date:	//

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

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

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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: 11311145

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. DELETED		[]		[]		Repeating Pages

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Incomplete, Data Complete, Deleted, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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

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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: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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: 11311145

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: 11311145

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: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

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?	

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (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: 11311145

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: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - 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: 11311145

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: V201_SURVEIL_CONSENT - Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - 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: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

Treatment Unblinded

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

Header Text: c4591001		Form: WITHDRAWAL OF CONSENT
Visit: Disposition - Unscheduled		Form Status: Not Started
Form Version: 22-Apr-2020 21:03		Site Name: (1131) PriMED Clinical Research
Site No: 1131		Subject Initials: ---
Subject No: 11311145		Generated Time (GMT): 29-Mar-2021 11:34
Generated By: (b) (4)		
Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/7/2020

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: 11311145

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1131

Subject No: 11311145

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

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Item	Date	User	Comment
Form	Sep-08-2020 16:43:03 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

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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Item	Date	User	Comment
1.b	Sep-08-2020 16:47:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	etiology, side effect of torsemide

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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.b	Sep-08-2020 16:47:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	etiology, side effect of torsemide

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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.b	Sep-08-2020 16:47:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	etiology, side effect of torsemide

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

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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Item	Date	User	Comment
1.b	Sep-08-2020 16:47:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	etiology, side effect of torsemide

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: DATE OF VISIT - 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
1	Sep-29-2020 13:34:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Vaccine delay for visit 2; investigator concerned about stability of patient, had four AEs due to starting a new diuretic medication. <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
Form	Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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
1	Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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
2.a	Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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
2.a	Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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
2.a	Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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](#)

Item	Date	User	Comment
Form	Dec-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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
1	Dec-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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
2	Dec-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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
4	Dec-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
Form	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
1	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Jan-04-2021 09:23:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Dec-31-2020 13:27:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	not applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
2	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
4	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Dec-30-2020 13:50:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Dec-28-2020 10:44:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
5	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
6	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
6	Dec-29-2020 11:28:52 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
7	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
8	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
9	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
10	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VACCINATION - 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
11	Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
11	Dec-29-2020 11:29:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
10	Sep-29-2020 09:20:52 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Delayed vaccine administration for visit 2, per investigator

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
10	Sep-29-2020 09:22:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Delayed vaccine administration for visit 2, per investigator

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
10	Sep-29-2020 09:25:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Delayed vaccine administration for visit 2, per investigator

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Oct-23-2020 17:26:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Syncopal episode, concomitant medications adjustment

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Oct-23-2020 17:42:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Medications adjustment during hospitalization

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: 11311145

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	Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

William Randall	Approved	Nov-10-2020 15:18:07 (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.

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1131

Subject No: 11311145

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
Sep-08-2020 16:42:03 (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
Sep-08-2020 16:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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
Sep-08-2020 16:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/8/2020	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

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: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-08-2020 16:41:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11311145	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1944	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-08-2020 16:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-08-2020 16:42:32 (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
Sep-08-2020 16:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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
Sep-08-2020 16:42:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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-08-2020 16:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-08-2020 16:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-08-2020 16:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	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: 11311145

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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I.a

Date	Location	User	Value	Reason
Sep-08-2020 16:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 1 er: Medical History decreased hearing in Term: both ears Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 16:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: decreased hearing in both ears	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:46:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-08-2020 16:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2	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: 11311145

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: dizziness Start Date: Jan/UNK/2020 Ongoing: NO End Date: Aug/UNK/2020	
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:47:12 (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-08-2020 16:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: dizziness	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Aug/UNK/2020	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-08-2020 16:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: full denture wearer Start Date: UNK/UNK/2015 Ongoing: YES	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: 11311145

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.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:07 (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-08-2020 16:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: full denture wearer	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-08-2020 16:48:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: eye glass wear Start Date: UNK/UNK/194 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:25 (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-08-2020 16:48:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: eye glass wearer	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1949	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:25 (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-08-2020 16:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: bilateral cataracts Start Date: UNK/UNK/2018 Ongoing: NO End Date: Mar/UNK/2020	Initial Entry

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Header Text: c4591001

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Subject No: 11311145

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

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I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 16:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral cataracts	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/UNK/2020	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-08-2020 16:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History: cataract surgery in both eyes Term: Start Date: Mar/UNK/2020 Ongoing: NO End Date: Mar/UNK/2020	Initial Entry

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Header Text: c4591001

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Site No: 1131

Subject No: 11311145

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: ---

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I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:49:18 (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-08-2020 16:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cataract surgery in both eyes	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/UNK/2020	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/UNK/2020	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-08-2020 16:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: chronic obstructive pulmonary disease, severe Start Date: Jan/UNK/2019 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11311145

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: ---

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I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:49:53 (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 15:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-09-2020 11:35:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per coordinator, subject had no systemic steroid 28 days prior to enrollment and met Inclusion 3.
Sep-09-2020 10:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 1: Opened	CLINQUERY - COPD is reported as SEVERE. Please confirm subject had no systemic steroid 28 days prior to enrollment and met Inclusion 3.
Sep-08-2020 16:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: chronic obstructive pulmonary disease, severe	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2019	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

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Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Sep-08-2020 16:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: atrial fibrillation Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry
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I.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 16:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: atrial fibrillation	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-09-2020 11:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 9 Medical History Term: edema in both legs Start Date: UNK/UNK/2016 Ongoing: YES	Changed Information

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Subject No: 11311145

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: ---

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Sep-08-2020 16:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Initial Entry edema in both legs and ankles UNK/UNK/2016 YES
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Li Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 14:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-09-2020 11:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: edema in both legs	Changed Information
Sep-09-2020 11:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Sep-09-2020 00:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term EDEMA IN BOTH LEGS AND ANKLES . Split the term into EDEMA IN BOTH LEGS and EDEMA IN BOTH ANKLES. Thank you.

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Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Date	Location	User	Value	Reason
Sep-08-2020 16:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: edema in both legs and ankles	Initial Entry

L.i Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

L.i Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

L.j

Date	Location	User	Value	Reason
Sep-08-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: elevated cholesterol, specific level unknown Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

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1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:51:49 (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-08-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: elevated cholesterol, specific level unkn own	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.k

Date	Location	User	Value	Reason
Sep-08-2020 16:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Te coronary artery dis rm: ease Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

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Subject No: 11311145

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

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 16:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: coronary artery disease	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Sep-08-2020 16:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: heart failure with reserved ejection fraction Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1131

Subject No: 11311145

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:53:23 (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-08-2020 16:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: heart failure with reserved ejection fraction	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:53:23 (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-08-2020 16:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Sep-08-2020 16:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 r: Medical History Term: urinary incontinence, urge Start Date: Aug/UNK/2019 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1131

Subject No: 11311145

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Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

1.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:53:49 (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-08-2020 16:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: urinary incontinence, urge	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/UNK/2019	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:53:49 (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-08-2020 16:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History benign prostatic hyperplasia Term: Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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I.n Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:56:25 (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 15:45:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-09-2020 11:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Sep-09-2020 10:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - BENIGN PROSTATIC HYPERPLASIA reports an END DATE. If a surgery was performed, please record in MH as a separate entry.
Sep-08-2020 16:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: benign prostatic hyperplasia	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

I.o

Date	Location	User	Value	Reason
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Sep-18-2020 10:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 15 Medical History Term: diabetic neuropathy of feet, bilaterally Start Date: UNK/UNK/2011 Ongoing: YES	Transcription Error
Sep-10-2020 09:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 15 Medical History Term: diabetic neuropathy of legs and feet Start Date: UNK/UNK/2011 Ongoing: YES	updated with location
Sep-08-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 15 Medical History Term: diabetic neuropathy Start Date: UNK/UNK/2011 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11311145

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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I.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:57:29 (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-18-2020 10:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diabetic neuropathy of feet, bilaterally	Transcription Error
Sep-10-2020 15:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-10-2020 09:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated with location
Sep-10-2020 09:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diabetic neuropathy of legs and feet	updated with location
Sep-09-2020 10:32:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please specify body site/location of condition DIABETIC NEUROPATHY.
Sep-08-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diabetic neuropathy	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.p

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Subject No: 11311145

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Date	Location	User	Value	Reason
Sep-18-2020 10:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 16 Medical History Term: peripheral neuropathy of feet, bilaterally Start Date: Apr/UNK/2019 Ongoing: YES	Changed Information
Sep-10-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 16 Medical History Term: peripheral neuropathy of legs and feet Start Date: Apr/UNK/2019 Ongoing: YES	updated with body location
Sep-08-2020 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 : Medical History Term: peripheral neuropathy Start Date: Apr/UNK/2019 Ongoing: YES	Initial Entry

1.p Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:57:52 (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-18-2020 10:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: peripheral neuropathy of feet, bilaterally	Changed Information
Sep-10-2020 15:44:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-10-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated with body location

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

Date	Location	User	Value	Reason
Sep-10-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: peripheral neuropathy of legs and feet	updated with body location
Sep-09-2020 10:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please specify body site/location of condition PERIPHERAL NEUROPATHY.
Sep-08-2020 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: peripheral neuropathy	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2019	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.q

Date	Location	User	Value	Reason
Sep-08-2020 16:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N umber: 17 Medical History Term: diabetes type II without a history of ketoacidosis Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry
Sep-08-2020 16:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 17	Initial Entry

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			Medical History Term: diabetes type II without any history of ketoacidosis Start Date: Ongoing:	
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I.q Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 16:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diabetes type II without any history of ketoacidosis	Initial Entry

I.q Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.q Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.r

Date	Location	User	Value	Reason
Sep-08-2020 16:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 Medical History Term: osteoporosis Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

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L.r Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

L.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 16:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: osteoporosis	Initial Entry

L.r Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

L.r Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

L.s

Date	Location	User	Value	Reason
Sep-08-2020 16:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 19 ber: Medical Histor eczema, bilaterally in a y Term: rms and legs Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11311145

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I.s Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 16:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: eczema, bilaterally in arms and legs	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.t

Date	Location	User	Value	Reason
Sep-08-2020 16:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 20 Medical History Term: insomnia Start Date: UNK/UNK/2011 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11311145

Generated By: (b) (4)

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I.t Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 16:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: insomnia	Initial Entry

I.t Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

I.t Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 16:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.u

Date	Location	User	Value	Reason
Sep-09-2020 11:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 21 Medical History Term: edema in ankles Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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I.u Line/MH Number:

Date	Location	User	Value	Reason
Sep-09-2020 11:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 11:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: edema in ankles	Initial Entry

I.u Start Date:

Date	Location	User	Value	Reason
Sep-09-2020 11:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.u Ongoing:

Date	Location	User	Value	Reason
Sep-09-2020 11:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.v

Date	Location	User	Value	Reason
Sep-09-2020 11:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 22 ber: Medical Histor transurethral resection y Term: of prostate Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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.v Line/MH Number:

Date	Location	User	Value	Reason
Sep-09-2020 11:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 11:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: transurethral resection of prostate	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Sep-09-2020 11:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
Sep-09-2020 11:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

I.w

Date	Location	User	Value	Reason
Sep-18-2020 11:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 23 Medical History Term: high blood pressure Start Date: UNK/UNK/2012 Ongoing: YES	New Information
Sep-18-2020 10:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 23 Medical History Term: high blood pressure Start Date: Oct/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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.w Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 10:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 10:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: high blood pressure	Initial Entry

I.w Start Date:

Date	Location	User	Value	Reason
Sep-18-2020 11:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	New Information
Sep-18-2020 10:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/UNK/2019	Initial Entry

I.w Ongoing:

Date	Location	User	Value	Reason
Sep-18-2020 10:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.x

Date	Location	User	Value	Reason
Sep-18-2020 10:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 24 Medical History Term: chronic kidney disease, stage 3 Start Date: Oct/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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.x Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 10:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 10:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: chronic kidney disease, stage 3	Initial Entry

I.x Start Date:

Date	Location	User	Value	Reason
Sep-18-2020 10:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/UNK/2019	Initial Entry

I.x Ongoing:

Date	Location	User	Value	Reason
Sep-18-2020 10:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1131

Subject No: 11311145

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

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1. Date:

Date	Location	User	Value	Reason
Sep-08-2020 16:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-08-2020 16:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 92.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-08-2020 16:44:04 (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-08-2020 16:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 186.2	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-08-2020 16:44:04 (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-08-2020 16:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26.5	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1131

Subject No: 11311145

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

Sep-08-2020 16:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-08-2020 16:44:04 (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-08-2020 16:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-08-2020 16:44:04 (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-08-2020 16:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311145

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-08-2020 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-08-2020 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 252464	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

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-08-2020 16:44:31 (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-08-2020 16:44:31 (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-08-2020 19:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 16:44:31 (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-08-2020 16:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-08-2020 19:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6DS5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 19:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6DS5	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1131
 Subject No: 11311145
 Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.b

Date	Location	User	Value	Reason
Sep-08-2020 19:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9W09	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 19:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9W09	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-08-2020 19:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9W0B	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 19:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9W0B	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (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: 11311145

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-08-2020 16:44:40 (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-08-2020 16:44:40 (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-08-2020 19:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 16:44:40 (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-08-2020 16:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-08-2020 19:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6DZ4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 19:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6DZ4	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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-08-2020 16:45:31 (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-08-2020 16:45:31 (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-08-2020 16:45:31 (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-08-2020 16:45:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020 13:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-08-2020 16:45:31 (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-08-2020 16:45:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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

Sep-08-2020 16:45:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-08-2020 16:45:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION 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-08-2020 16:45:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1131

Subject No: 11311145

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-08-2020 16:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJE CT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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
Sep-29-2020 13:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001
Visit: V2_VAX2_L
Form Version: 10-Dec-2020 02:27
Site No: 1131
Subject No: 11311145
Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1131) PriMED Clinical Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:34

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I. Date:

Date	Location	User	Value	Reason
Jan-05-2021 01:53:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Jan-04-2021 00:35:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Candidate	DMW6678847;Vitals Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-31-2020 13:28:19 (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-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Temperature: Not Applicable Temperature Unit: Not Applicable Temperature Location :: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Dec-31-2020 13:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (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, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311145**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-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-05-2021 06:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Jan-03-2021 23:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Candidate	DMW6678864;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	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-31-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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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I. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-06-2021 03:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-05-2021 09:40:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	not applicable bottom is check on the form please advice on what needs to be done again
Jan-05-2021 02:32:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Please add form level comment 'Not Applicable' in this form. Thank you.
Jan-04-2021 09:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-04-2021 09:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	LTFU
Jan-04-2021 09:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	LTFU
Jan-04-2021 04:30:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Please remove form data including Temp Delay details using eraser icon and then apply fresh 'Not Applicable' form level comment. Refer to section 4.10/4.13 of completion guidelines.
Dec-31-2020 13:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This has been updated to all forms except temp delay form. thanks
Dec-31-2020 04:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM2: Form level comment 'Not applicable' is still missing in this CRF. Please update.
Dec-30-2020 13:51:08 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	data updated

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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

(US & Canada)		(b) (4), (b) (6)		
Dec-30-2020 04:29:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thank you for response. Please consider to update form level comment as 'not applicable'. Else, clarify.
Dec-29-2020 11:29:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	data updated
Dec-29-2020 00:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: As subject is not vaccinated and LTFU then consider marking this, form as Not Applicable by selecting form level comment. Ask CRA in case any assistance if needed. Thank you.
Dec-29-2020 00:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	new query issued
Dec-28-2020 10:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated
Dec-24-2020 01:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please clear existing data and add form level 'Not Done' comment on all the initiated forms of this visit per section 4.10 of completion guidelines.
Dec-23-2020 09:38:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	visit 2 was initiated. Subject came in but was not vaccinated. Visit was delayed but subject ended up being LTFU.
Dec-23-2020 02:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Per EOT visit data, subject is LTFU. If correct then kindly verify if V2VX2L visit is performed, If not then clear data and add form level comment 'Not Done/Not

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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

				Applicable' on all the initiated forms of this visit to avoid yellow traffic light.
Dec-09-2020 04:32:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Query to be actioned once appropriate forms are updated for discontinued patient.
Dec-08-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The USPS are delivering a certified letter. USPS attempts a few times. We are waiting for a successful delivery notification. Per protocol, we need to respond to queries within 24 hours so we respond. We will update EDC when we receive the USPS notificatio
Dec-08-2020 02:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for the response. Please update applicable forms for discontinued patient once confirmation is available and respond to this query. Thank you.
Dec-07-2020 09:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject to be discontinued. Certified letter sent to subject on 04DEC2020. Waiting on confirmation of delivery.
Dec-07-2020 09:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thanks for the response, however kindly verify recent subject status if vaccinated update this visit with vaccination details or if discontinued then consider updating applicable forms for discontinued patient or else clarify. Thank

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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

				you.
Nov-16-2020 15:05:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Physician and coordinator still assessing subject status moving forward. EDC will be updated. Please check in a few days.
Nov-16-2020 08:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Physician and coordinator still assessing subject status moving forward. EDC will be updated when determined.
Nov-14-2020 22:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please verify recent subject status if vaccinated update this visit with vaccination details or if discontinued then consider updating applicable forms for discontinued patient or else clarify. Thank you.
Sep-29-2020 13:31:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Sep/28/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-30-2020 13:50:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-28-2020 10:44:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Dec-22-2020 02:34:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-21-2020 13:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	vaccine was not administered
Dec-21-2020 09:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW6542509;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.
Oct-23-2020 03:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 08:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per coordinator, physician deemed this subject will not be receiving Vaccination 2 due to recent hospitalization. SAE is being submitted today.

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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

Oct-21-2020 11:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Please confirm the status of the vaccination 2, please update the CRF if received. Else clarify.
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-29-2020 11:28:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-04-2021 09:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311145

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

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

Date	Location	User	Value	Reason
Dec-29-2020 11:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

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
Dec-10-2020 12:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-10-2020 12:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-16-2020 12:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Dec-16-2020 12:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Dec-16-2020 09:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Subject reported to be LTFU as reason for end of treatment. Please review if the same status should be applied at the FUP tab to indicate end of study
Dec-10-2020 12:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-10-2020 12:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is LOST TO FOLLOW-UP but "Specify Status" is missing.
Dec-10-2020 12:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LOST TO FOLLOW-UP	Initial Entry

4. Specify Status:

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - 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

Date	Location	User	Value	Reason
Dec-10-2020 12:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject has not reached out to site after repeated attempts. Certified letter deliv ered 07DEC2020	Initial Entry

Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1131**Subject No:** 11311145**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-16-2020 12:05:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is LOST TO FOLLOW-UP but "Specify Status" is missing.
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LOST TO FOLLOW-UP	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Dec-16-2020 12:05:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject has not reached out to site after r epeated attempts. Certified letter deliver ed 07DEC2020	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Sep-29-2020 09:20:12 (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: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-29-2020 09:22:18 (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: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-29-2020 09:24:44 (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: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-29-2020 09:26:20 (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: 11311145

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-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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-23-2020 17:34:24 (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: 11311145

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-23-2020 17:40:55 (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: 11311145

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-27-2020 13:13:30 (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: 11311145

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
Nov-23-2020 09:05:57 (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: 11311145

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
Nov-23-2020 09:07:42 (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: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-23-2020 09:09:19 (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: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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
Sep-29-2020 09:20:12 (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
Sep-29-2020 09:20:12 (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-27-2020 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Oct-27-2020 11:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Adjustment of cardiac medications
Oct-27-2020 11:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for your response. Could you please specify which treatment the falls are related to?
Oct-26-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Per PI, type of falls were not "mechanical".
Oct-26-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Frequent falls	Per PI, type of falls were not "mechanical".
Oct-26-2020 11:32:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative falls started three months ago and are related to current drug treatment. Please specify which treatment is related to. Thank you.
Sep-29-2020 09:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mechanical falls	Initial Entry

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Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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4. Start Date Time:

Date	Location	User	Value	Reason
Sep-29-2020 09:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-06-2021 09:11:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-05-2021 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject has not reached out to site and we have lost follow up.
Jan-05-2021 14:41:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Dec-16-2020 23:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-16-2020 12:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	disposition form does not appear to be filled out for this subject when looking in EDC. However, since the site can not get into contact with subject (LTFU) the end date is unknown for this AE
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-12-2020 21:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 16:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	From last contact, this AE is ongoing.

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Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

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Subject Initials: ---

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Nov-12-2020 15:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Sep-29-2020 09:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-29-2020 09:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-29-2020 09:20:12 (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
Sep-29-2020 09:20:12 (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-01-2020 10:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Sep-30-2020 10:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per coordinator, subject started and stopped a diuretic, Toresmide, 20mg

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Subject No: 11311145

Generated By: (b) (4)

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				daily, AND Duloxetine, 20mg daily for peripheral neuropathy. Subject to be evaluated by his own primary care physician for further evaluation for cause of multiple symptoms.
Sep-30-2020 10:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julen Gayed (b) (4)	Query 1: Opened	Clin: Please provide details of the concomitant drugs that caused this AE
Sep-29-2020 09:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-29-2020 09:20:12 (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
Sep-29-2020 09:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-29-2020 09:20:12 (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
Sep-29-2020 09:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 09:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Subject No: 11311145

Generated By: (b) (4)

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Form Status: Data Complete

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Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Sep-29-2020 09:22:18 (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
Sep-29-2020 09:22:18 (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
Sep-29-2020 13:27:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-29-2020 12:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-29-2020 12:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: abrasion of right forea rm	Changed Information
Sep-29-2020 12:14:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term ABRASION WITH BRUISING OF RIGHT FOREARM. Split the term into ABRASION OF RIGHT FOREARM and BRUISING OF RIGHT FOREARM and report as separate entries. Thank

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				you.
Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: abrasion with bruising of right forearm	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-06-2021 09:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-05-2021 15:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject has not reached out to site and we have lost follow up.
Jan-05-2021 14:41:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Dec-16-2020 23:22:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-16-2020 12:08:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	disposition form does not appear to be filled out for this subject when looking in EDC. However, since the site can not get into contact with subject (LTFU) the end date is unknown for this AE
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.

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Nov-12-2020 21:43:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 16:02:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Since last contact, this AE is ongoing.
Nov-12-2020 15:56:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-29-2020 09:22:18 (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
Sep-29-2020 09:22:18 (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
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Site No: 1131

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Mar-03-2021 14:15:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-03-2021 11:03:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	subject stated that it started after 18sep2020 when he started taking duloxetine
Mar-03-2021 09:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Causality is reported as OTHER - CONCOMITANT DRUG TREATMENT. Please confirm a medication caused Abrasion Rt Arm or update as applicable. If cause was a AE 1(fall), please update.
Oct-01-2020 10:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Sep-30-2020 10:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per coordinator, subject started and stopped a diuretic, Toresmide, 20mg daily, AND Duloxetine, 20mg daily for peripheral neuropathy. Subject to be evaluated by his own primary care physician for further evaluation for cause of multiple symptoms.
Sep-30-2020 10:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please provide details of the concomitant drugs that caused this AE
Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-29-2020 09:22:18 (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
Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 09:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

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Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Sep-29-2020 09:24:44 (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
Sep-29-2020 09:24:44 (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
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tingling of bilateral limbs, intermittent	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-06-2021 09:13:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-05-2021 15:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject has not reached out to site and we have lost follow up.
Jan-05-2021 14:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311145**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-16-2020 23:22:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-16-2020 12:09:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	disposition form does not appear to be filled out for this subject when looking in EDC. However, since the site can not get into contact with subject (LTFU) the end date is unknown for this AE
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-13-2020 10:29:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Nov-12-2020 13:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	At last contact, adverse event still ongoing. Thank you.
Nov-12-2020 10:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm if this AE is still ongoing?
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject No: 11311145

Generated By: (b) (4)

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Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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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
Sep-29-2020 09:24:44 (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-01-2020 10:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Sep-30-2020 10:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per coordinator, subject started and stopped a diuretic, Toresmide, 20mg daily, AND Duloxetine, 20mg daily for peripheral neuropathy. Subject to be evaluated by his own primary care physician for further evaluation for cause of multiple symptoms.
Sep-30-2020 10:16:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please provide details of the concomitant drugs that caused this AE
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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(US & Canada)

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-29-2020 09:24:44 (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
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 09:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Generated By: (b) (4)

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Form Status: Data Complete

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1. Category:

Date	Location	User	Value	Reason
Sep-29-2020 09:26:20 (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
Sep-29-2020 09:26:20 (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
Dec-03-2020 13:06:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Previous answer was sent in error. Apologies. Appreciate the response. Thank you.
Dec-03-2020 08:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	FU report has been submitted.
Dec-03-2020 02:33:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Response does not satisfy query
Dec-02-2020 18:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Response does not satisfy query
Nov-30-2020 15:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Coordinator will review records and submit FU report as needed.
Nov-30-2020 15:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative for the AE of Orthostatic Hypotension (AE #6 of this log), " blood pressures remained soft so was not continued at discharge". Please specify Blood pressure

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				values in a FU report. Thank you.
Sep-29-2020 09:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: generalized weakness, intermittent	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-29-2020 09:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-06-2021 09:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-05-2021 15:54:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject has not reached out to site and we have lost follow up.
Jan-05-2021 14:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.
Dec-17-2020 01:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed as per site response.
Dec-16-2020 12:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	disposition form does not appear to be filled out for this subject when looking in EDC. However, since the site can not get into contact with subject (LTFU) the end date is unknown for this AE
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.

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Nov-13-2020 10:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Nov-12-2020 13:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	At last contact, adverse event still ongoing. Thank you.
Nov-12-2020 10:39:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm if this AE is still ongoing?
Sep-29-2020 09:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-29-2020 09:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-29-2020 09:26:20 (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
Sep-29-2020 09:26:20 (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-01-2020 10:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311145**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Sep-30-2020 10:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per coordinator, subject started and stopped a diuretic, Toremside, 20mg daily, AND Duloxetine, 20mg daily for peripheral neuropathy. Subject to be evaluated by his own primary care physician for further evaluation for cause of multiple symptoms.
Sep-30-2020 10:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please provide details of the concomitant drugs that caused this AE
Sep-29-2020 09:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: CONCOMITANT DRUG TREATM ENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-29-2020 09:26:20 (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
Sep-29-2020 09:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-29-2020 09:26:20 (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
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Sep-29-2020 09:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-29-2020 09:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-22-2020 18:39:15 (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-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-27-2020 05:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	SDB updated
Oct-27-2020 02:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	SAE RECON: To check SAE listing if updates will be reflected
Oct-26-2020 15:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Updated report was sent to safety on 23OCT2020 with updated term.
Oct-24-2020 11:39:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020411549,the term was updated to SYNCOPE in AE CRF while recorded as 'syncope and collapse secondary to orthostatic hypotension' in Safety DB.Please confirm.If safety update is required, please submit a follow-up'

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Generated By: (b) (4)

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Oct-24-2020 01:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-23-2020 17:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-23-2020 17:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Syncope	Changed Information
Oct-23-2020 06:20:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple actions for SYNCOPE AND COLLAPSE SECONDARY TO ORTHOSTATIC HYPOTENSION: Split the term into SYNCOPE SECONDARY TO ORTHOSTATIC HYPOTENSION and COLLAPSE and also specify further whether reporting CIRCULATORY COLLAPSE or other and update as such. Thank you.
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Syncope and collapse secondary to orthostatic hypotension	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/13/2020 UNK:UNK	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-23-2020 05:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Syncope and collapse secondary to orthostatic hypotension: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistence	Initial Entry

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			nt or significant disability/incapacity? NO	
			Is this serious event life threatening? NO	
			Other medically important serious event NO	

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

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

Date	Location	User	Value	Reason
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-28-2020 11:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-26-2020 15:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Associated event is noted as hypovolemia.
Oct-24-2020 02:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissue d:Opened	DM: Kindly verify and confirm if there is any associated event reported if yes, please update event here or else clarify via query response.
Oct-23-2020 17:23:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

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<p>Oct-23-2020 17:23:51 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> Hypotension</p>	<p>Changed Information</p>
<p>Oct-23-2020 02:48:56 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>PFE SDQ PROD (b) (4)</p>	<p>Query 1: Opened</p>	<p>Please review "If not related to study treatment other" field, the following text was indicated in the comment field [hypotension,Dehydration,Atrial Fibrillation,RVR]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)</p>
<p>Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment</p>	<p>Initial Entry</p>

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			<p>atment (s), thi s event is due t o:</p> <p>OTH ER</p> <p><i>If O ther , sp ecif y:</i></p> <p>O rt ho st ati c hy po te ns io n, D eh yd ra ti on an d At ri al Fi br ill ati on wi th R V R</p>
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311145**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-27-2020 05:51:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB UPDATED
Oct-27-2020 02:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON: To check SAE listing if updates will be reflected
Oct-26-2020 15:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated report was sent to safety on 23OCT2020 with action taken corrected to: Not Applicable.
Oct-26-2020 07:16:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: Per latest SAE listing action taken is still reported as permanently withdrawn. If not applicable is the correct action taken, please confirm if a follow up AEM form was submitted to update action taken in Safety database.
Oct-24-2020 09:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON: Pending SDB update
Oct-23-2020 17:25:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	After PI review, safety update will be submitted.
Oct-23-2020 05:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020411549 ,action taken was reported as NOT APPLICABLE in AE CRF while PERMANENTLY WITHDRAWN in Safety database.Please confirm.If safety update is required,please submit a follow up
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 18:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-23-2020 05:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2020411549	Initial Entry

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Subject No: 11311145

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-22-2020 18:40:47 (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-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-27-2020 05:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB updated
Oct-27-2020 02:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON: To check SAE listing if updates will be reflected
Oct-26-2020 15:05:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Follow up report was sent to safety with updated term on 23OCT2020.
Oct-24-2020 11:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020411512,the term was updated to 'Hypotension, orthostatic' in AE CRF while reported as 'hypotension' in Safety database . Please confirm correct term.If safety update is required, please submit a follow-up form.
Oct-23-2020 17:27:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypotension, orthostatic	Changed Information
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypotension	Initial Entry

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(US & Canada)

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

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-24-2020 09:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 19:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020 UNK:UNK	Transcription Error
Oct-23-2020 17:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020 UNK:UNK	Changed Information
Oct-23-2020 12:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 12:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020 UNK:UNK	Transcription Error
Oct-23-2020 05:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020411512
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 14:03:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UNK:UNK	New Information
Oct-23-2020 19:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Oct-23-2020 17:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/13/2020 UNK:UNK	New Information
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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(US & Canada)

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-23-2020 05:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hypotension: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Is this serious event associated with co ngenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolo ng hospitalization? YES Did this serious event result in persiste nt or significant disability/incapacity? NO Is this serious event life threatening?	Initial Entry

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			NO	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Oct-22-2020 18:40:47 (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-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Hypovolemia due to poor oral intake	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-22-2020 18:40:47 (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
Oct-27-2020 05:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB updated
Oct-27-2020 02:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON: To check SAE listing if updates will be reflected
Oct-26-2020 15:08:46 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated report was sent to safety on 23OCT2020 with

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(US & Canada)		(b) (4), (b) (6)		action taken updated to Not Applicable.
Oct-24-2020 11:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020411512 ,action taken was reported as NOT APPLICABLE in AE CRF while PERMANENTLY WITHDRAWN in Safety database.Please confirm. If safety update is required, please submit a follow up form
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 07:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Nov-09-2020 08:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Outcome correct. Will update safety report accordingly.
Nov-07-2020 10:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	SAE RECON:AER# 2020411512 ,outcome was updated to RECOVERED/RESOLVEDin AE CRF form however, reported as Recovering/Resolvingto Safety DB.Please confirm correct outcome. If safety update is required, please submit a follow-up form
Nov-06-2020 14:03:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query

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Nov-06-2020 14:03:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-06-2020 14:03:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE Hypotension, orthostatic: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 05:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	SDB updated
Oct-27-2020 02:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	SAE RECON: To check SAE listing if updates will be reflected
Oct-26-2020 16:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Report was updated and faxed to safety today, 26OCT2020 to indicate "resolving".
Oct-24-2020 11:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER# 2020411512 ,outcome was updated to RECOVERING/RESOLVING in AE CRF form however, reported as NOT RECOVERED/NOT RESOLVED to Safety DB.Please confirm correct outcome. If safety update is required, please submit a follow-up form
Oct-23-2020 19:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-23-2020 19:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Transcription Error
Oct-23-2020 19:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Hypotension, orthostatic: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-23-2020 17:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Oct-23-2020 17:29:55	ACV0PFEINFP6000	auto query	Query 1: Closed	Close Auto Query

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(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Oct-23-2020 17:29:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED WITH SEQUELAE	Changed Information
Oct-23-2020 17:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Hypotension, orthostatic: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 18:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-23-2020 05:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020411512	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311145**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[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-23-2020 17:34:24 (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-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypovolemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

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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-23-2020 17:34:24 (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-23-2020 17:34:24 (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-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: due to poor intake	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-23-2020 17:34:24 (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
Oct-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

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Date	Location	User	Value	Reason
Oct-23-2020 17:34:24 (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-23-2020 17:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Oct-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED WITH SE QUELAE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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

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1. Category:

Date	Location	User	Value	Reason
Oct-23-2020 17:40:55 (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-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-09-2020 07:03:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Nov-06-2020 15:35:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Appreciate the response. Thank you very much.
Nov-05-2020 16:46:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	FU reports for this subjects 2 SAE's- Orthostatic Hypotension and Syncope will indicate the COVID test status.
Nov-05-2020 07:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	per Data Monitoring Committee, each hospitalized subject requires a report of COVID test status. If test performed = YES/No/Not available (in any case), kindly provide FU report with results/status. Thank you.
Nov-04-2020 20:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	per Data Monitoring Committee, each hospitalized subject requires a report of

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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				COVID test status. If test performed = YES/No/Not available (in any case), kindly provide FU report with results/status. Thank you.
Nov-04-2020 10:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per coordinator/site manager, follow-up reports only indicated for SAEs and AFib RVR is an AE. No NAAT was performed.
Nov-03-2020 14:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Appreciate the response. Thank you.
Nov-03-2020 12:04:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Appreciate the response. Thank you.
Nov-03-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Understood. Follow up report being filed today.
Nov-02-2020 17:15:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for the prompt response. Was there any other type of covid test performed during hospitalization? If so, please provide information (Not available or results) on a FU report. Thank you.
Nov-02-2020 09:13:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	NAAT test not done in regards to this adverse event.
Nov-01-2020 21:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Kindly confirm if any SARS-CoV-2 (NAAT or other) tests were performed on the SAE submitted to safety. If test performed = YES, please provide FU report with results. If test was NOT done or NOT available, please FU as well. Thanks

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Generated By: (b) (4)

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Oct-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Atrial fibrillation with rapid ventricular response	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-23-2020 17:40:55 (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-23-2020 17:40:55 (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:

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Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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: ---

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Date	Location	User	Value	Reason
Oct-27-2020 09:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 08:59:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This symptom has been listed separately as an adverse event but, per physician and investigator, the etiology of the Afib was due to hypovolemia.
Oct-27-2020 07:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Hypovolemia]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Oct-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Hypovolemia	Initial Entry

10. Latest Action Taken with Study Treatment:

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Header Text: c4591001

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Site No: 1131

Subject No: 11311145

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

Date	Location	User	Value	Reason
Oct-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-23-2020 17:40:55 (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-23-2020 17:40:55 (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-23-2020 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

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Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-16-2020 15:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Appreciate the FU. Thank you.
Nov-16-2020 13:54:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Per coordinator, AE log will be updated by Wednesday once case subject status confirmed. The study team thanks you for your patience.
Nov-15-2020 16:52:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	Per case narrative, the subject has two additional events not recorded in AE log (diabetic foot ulcer and acute kidney injury (AKI). Kindly revise and update AE log accordingly. Thank you.
Nov-09-2020 07:03:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Nov-06-2020 15:35:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Candidate	Appreciate the response. Thank you very much.

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Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

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Nov-05-2020 16:46:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	FU reports for this subjects 2 SAE's- Orthostatic Hypotension and Syncope will indicate the COVID test status.
Nov-05-2020 07:50:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	per Data Monitoring Committee, each hospitalized subject requires a report of COVID test status. If test performed = YES/No/Not available (in any case), kindly provide FU report with results/status. Thank you.
Nov-04-2020 20:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Candidate	per Data Monitoring Committee, each hospitalized subject requires a report of COVID test status. If test performed = YES/No/Not available (in any case), kindly provide FU report with results/status. Thank you.
Nov-04-2020 10:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per coordinator/site manager, follow-up reports only indicated for SAEs and Hypovolemia is an AE. No NAAT was performed.
Nov-03-2020 14:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Appreciate the response. Thank you.
Nov-03-2020 12:04:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Candidate	Appreciate the response. Thank you.
Nov-03-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Understood. Follow up report being filed today.
Nov-02-2020 17:15:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Opened	Thank you for the prompt response. Was there any other type of

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				covid test performed during hospitalization? If so, please provide information (Not available or results) on a FU report. Thank you.
Nov-02-2020 09:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NAAT test not done in regards to this adverse event.
Nov-01-2020 21:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Kindly confirm if any SARS-CoV-2 (NAAT or other) tests were performed on the SAE submitted to safety. If test performed = YES, please provide FU report with results. If test was NOT done or NOT available, please FU as well. Thanks
Oct-28-2020 11:08:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thank you!
Oct-28-2020 10:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The coordinator will re-assess and update AE log appropriately. Thank you.
Oct-27-2020 14:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Please assess additional reported events on case report: dehydration, LVH, acute kidney injury (AKI), mitral valve regurgitation, acute on chronic renal failure. Kindly revise and update AE log accordingly. Thank you.
Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypovolemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 14:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UNK:UNK	New Information
Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-27-2020 13:13:30 (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-27-2020 13:13:30 (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-27-2020 13:13:30	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Inadequate intake	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 13:13:30 (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
Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 13:13:30 (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-06-2020 14:04:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 14:04:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-06-2020 14:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE hypovolemia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.

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Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-27-2020 13:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311145**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (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
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diabetic foot ulcer, right foot	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-06-2021 09:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-05-2021 15:54:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	subject has not reached out to site and we have lost follow up.
Jan-05-2021 14:43:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY - Please verify if AE is still ongoing, or update END DATE and OUTCOME as applicable.

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Dec-17-2020 09:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Close per query response
Dec-16-2020 12:09:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	disposition form does not appear to be filled out for this subject when looking in EDC. However, since the site can not get into contact with subject (LTFU) the end date is unknown for this AE
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (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
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

(US & Canada)

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

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER If Other, specify: Infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (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
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (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-23-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 09:05:57 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

(US & Canada)

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

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311145**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[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Nov-23-2020 09:07:42 (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
Nov-23-2020 09:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-23-2020 09:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: acute kidney injury	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 09:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 09:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-23-2020 09:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

Header Text: c4591001

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Site No: 1131

Subject No: 11311145

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-23-2020 09:07:42 (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
Nov-23-2020 09:07:42 (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
Nov-23-2020 09:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER If Other, specify: hypovolemia	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 09:07:42 (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
Nov-23-2020 09:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: c4591001

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Site No: 1131

Subject No: 11311145

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

Date	Location	User	Value	Reason
Nov-23-2020 09:07:42 (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-23-2020 09:07:42 (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
Nov-23-2020 09:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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
Nov-23-2020 09:09:19 (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
Nov-23-2020 09:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-23-2020 09:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: acute kidney injury	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 09:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 09:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-23-2020 09:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-23-2020 09:09:19 (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
Nov-23-2020 09:09:19 (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
Nov-23-2020 09:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER If Other, specify: hypovolemia	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 09:09:19 (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
Nov-23-2020 09:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

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

Date	Location	User	Value	Reason
Nov-23-2020 09:09:19 (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-23-2020 09:09:19 (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
Nov-23-2020 09:09:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: RADIATION TREATMENT - Audit Trail

Form Status:

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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

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Date	Location	User	Value	Reason
Oct-28-2020 10:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Deleted	deleting per DM request since there is no data

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311145

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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

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3. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-27-2020 09:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Query placed in different form.
Oct-26-2020 12:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	In case narrative records participant received influenza vaccine for health maintenance on 01Oct2020. Please update form accordingly. Thank you.

5. Start Date:

Date	Location	User	Value	Reason
Oct-29-2020 08:37:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-28-2020 10:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	deleting them now
Oct-28-2020 04:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please delete this logline if there is no data to be recorded.

090177e196ae3ea0\Final\Final On: 01-Apr-2021 04:56 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311145

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Dec-10-2020 12:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Sep-08-2020 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-08-2020 16:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-16-2020 12:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/7/2020	Initial Entry
Dec-10-2020 12:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/7/2020	Initial Entry
Sep-08-2020 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/8/2020	Initial Entry
Sep-08-2020 16:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/8/2020	Initial Entry

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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: 11311145

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 10:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry