

Header Text: c4591001
Visit: COHORT_SELECTION **Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1131 **Site Name:** (1131) PriMED Clinical Research
Subject No: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PRIMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/17/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PRIMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11311021]
2.	Birth Date:	(b) (6)/1947
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:	

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1131

Subject No: 11311021

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
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

eCRF Audit Trail History

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/17/2020
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: 11311021

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:	[Denture wearer, partial lower]
	Start Date:	UNK/UNK/1974
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperopia]
	Start Date:	UNK/UNK/1982
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High blood pressure]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2015

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraine headaches]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Blood transfusion]
	Start Date:	UNK/UNK/1973
	Ongoing:	NO End Date: UNK/UNK/1973
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Auto accident]
	Start Date:	UNK/UNK/1973
	Ongoing:	NO End Date: UNK/UNK/1973
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis, bilateral hands]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis, bilateral knees]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dermatitis, bilateral arms]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dermatitis, back]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Deviated septum]
	Start Date:	UNK/UNK/1973
	Ongoing:	NO End Date: UNK/UNK/1980

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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

1.1	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillectomy, surgery]
	Start Date:	UNK/UNK/1953
	Ongoing:	NO End Date: UNK/UNK/1953
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Deviated septum surgical repair]
	Start Date:	UNK/UNK/1980
	Ongoing:	NO End Date: UNK/UNK/1980
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[eye glass wearer]
	Start Date:	UNK/UNK/1982
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PRIMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/17/2020
2.	Weight:	[97.4]
3.	Unit:	kg
4.	Height:	[169.5]
5.	Unit:	cm
6.	Body Mass Index:	[33.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: RANDOMIZATION

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

eCRF Audit Trail History

Disposition

1.	Randomization Date :	Aug/17/2020
2.	Randomization Number:	[228819]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
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	[BN6DG4]
5.b	Sample ID	[BN6DG5]
5.c	Sample ID	[BN6DG6]
5.d	Sample ID	[BL9VS6]
5.e	Sample ID	[BL9VS7]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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: Aug/17/2020
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	[BN6DTH]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311021

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:	Aug/17/2020 10:28
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

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1131

Subject No: 11311021

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: 11311021

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PRiMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/9/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6DZL]
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311021

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/9/2020 08:25
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

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP99TX]
5.b	Sample ID	[BL9VK3]
5.c	Sample ID	[BL9VK4]

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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: 11311021

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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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (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: 11311021

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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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

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: 11311021

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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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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?	
----	--	--

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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: 11311021

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:	
----	-------------------------	--

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: 11311021

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	[]
----	-----------	-----

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1131

Site Name: (1131) PRIMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/9/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: 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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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	[]
----	-----------	-----

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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	Deep Vein Thrombosis	Mar/2/2021 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	Aortic Aneurysm	Mar/2/2021 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Pulmonary Embolism	Mar/2/2021 UNK:UNK	YES	Repeating Pages

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Not Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Deep Vein Thrombosis]
4.	Start Date Time:	Mar/2/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Not Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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: [Uncertain etiology]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
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	[2021247386]

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311021**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Incomplete, Not Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Aortic Aneurysm]
4.	Start Date Time:	Mar/2/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Not Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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: [Hypertension]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
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	[2021247386]

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311021**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Incomplete, Not Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pulmonary Embolism]
4.	Start Date Time:	Mar/2/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Not Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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: [Deep vein thrombosis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
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	[2021247386]

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Medication Error

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

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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:	//

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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?	

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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Radiation Treatment

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

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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: 11311021

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: 11311021

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: 11311021

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?	

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (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: 11311021

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: 11311021

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: 11311021

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

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: 11311021

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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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/28/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/28/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PRIMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1131

Site Name: (1131) PRIMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/9/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
William Randall	Approved	Mar-11-2021 13:52:07 (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.

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 30-Jul-2020 21:29
Site No: 1131
Subject No: 11311021
Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1131) PriMED Clinical Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-17-2020 13:30:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
William Randall	Approved	Mar-11-2021 13:52:07 (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.

(b) (6)	N/A	Jan-29-2021 09:33:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

William Randall	Approved	Oct-20-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PRiMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-17-2020 13:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-17-2020 13:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent O btained Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PRiMED Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-17-2020 13:29:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11311021	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:28:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1947	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LAT INO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Aug-17-2020 13:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-17-2020 13:30:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - 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: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-17-2020 13:30:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-17-2020 13:30:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Aug-17-2020 13:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Denture wearer, partial lower Start Date: UNK/UNK/1974 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Denture wearer, partial lower	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:31:44	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1974	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	
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1.a Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-17-2020 17:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 2 Medical History Term: Hyperopia Start Date: UNK/UNK/1982 Ongoing: YES	splitting terms
Aug-17-2020 13:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: N 2 Medical History Term: Hyperopia, eye glass wearer Start Date: UNK/UNK/1982 Ongoing: YES	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 20:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-17-2020 17:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	splitting terms
Aug-17-2020 17:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Hyperopia	splitting terms
Aug-17-2020 17:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term HYPEROPIA, EYE GLASS WEARER. Split the term

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

				into HYPEROPIA and EYE GLASS WEARER and report as 2 separate entries. Thank you.
Aug-17-2020 13:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Hyperopia, eye glass wearer	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1982	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-17-2020 13:33:11 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH Number: 3 Medical History Term: High blood pressure Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2015</p>	<p>Initial Entry</p>
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Aug-17-2020 13:33:11 (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
Aug-17-2020 13:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: High blood pressure	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Aug-17-2020 13:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 4 mber: Medical Histo Migraine he ry Term: adaches Start Date: UNK/UNK/ 1985 Ongoing: YES	Initial Entry
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Aug-17-2020 13:33:36 (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
Aug-17-2020 13:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Migraine headaches	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1985	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-17-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>13:34:19 (UTC-05:00) Eastern Time (US & Canada)</p>		<p>(autocalc)</p>	<p>Line/MH Number: 5 Medical History Term: Blood transfusion Start Date: UNK/UNK/1973 Ongoing: NO End Date: UNK/UNK/1973</p>	
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:34:19 (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
Aug-17-2020 13:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood transfusion	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1973	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1973	Initial Entry

I.f

Date	Location	User	Value	Reason
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-17-2020 13:36:48 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><u>Data Entry:</u> Line/MH Number: 6 Medical History Term: Auto accident Start Date: UNK/UNK/1973 Ongoing: NO End Date: UNK/UNK/1973</p>	<p>Initial Entry</p>
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34***1.f Line/MH Number:***

Date	Location	User	Value	Reason
Aug-17-2020 13:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Auto accident	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1973	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1973	Initial Entry

1.g

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-17-2020 13:37:15 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH N 7 umber: Medical Hi Osteoarthritis, story Term: bilateral hands Start Date: UNK/UNK/19 85 Ongoing: YES</p>	<p>Initial Entry</p>
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34***I.g Line/MH Number:***

Date	Location	User	Value	Reason
Aug-17-2020 13:37:15 (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
Aug-17-2020 13:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis, bilateral ha nds	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1985	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-17-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

13:37:46 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH Number: 8 Medical History Term: Osteoarthritis, bilateral knees Start Date: UNK/UNK/1985 Ongoing: YES	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Aug-17-2020 13:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis, bilateral kn ees	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1985	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-17-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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

13:38:16
(UTC-05:00) Eastern
Time (US & Canada)

(autocalc)

**Line/MH N
umber:** 9

**Medical His
tory Term:** Dermatitis, bi
lateral arms

Start Date: UNK/UNK/1
980

Ongoing: YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dermatitis, bilateral arms	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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I.j

Date	Location	User	Value	Reason
Aug-17-2020 13:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 10 ber: Medical History Term: Dermatitis, back Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:38:34 (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
Aug-17-2020 13:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dermatitis, back	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:38:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.k

Date	Location	User	Value	Reason
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-17-2020 13:39:10 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH Number: 11 Medical History Term: Deviated septum Start Date: UNK/UNK/1973 Ongoing: NO End Date: UNK/UNK/1980</p>	<p>Initial Entry</p>
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**1.k Line/MH Number:**

Date	Location	User	Value	Reason
Aug-17-2020 13:39:10 (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
Aug-17-2020 13:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Deviated septum	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1973	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1980	Initial Entry

1.l

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-17-2020 13:39:44 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH N 12 umber: Medical His Tonsillectom tory Term: y, surgery Start Date: UNK/UNK/1 953 Ongoing: NO End Date: UNK/UN K/1953</p>	<p>Initial Entry</p>
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Aug-17-2020 13:39:44 (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
Aug-17-2020 13:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tonsillectomy, surgery	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1953	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1953	Initial Entry

1.m

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-17-2020 13:40:09 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH 13 Number: Medical History Term: Deviated septum surgical repair Start Date: UNK/UNK/1980 Ongoing: NO End Date: UNK/UNK/ 1980</p>	<p>Initial Entry</p>
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34***1.m Line/MH Number:***

Date	Location	User	Value	Reason
Aug-17-2020 13:40:09 (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
Aug-17-2020 13:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Deviated septum surgical repair	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 13:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1980	Initial Entry

1.n

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Aug-17-2020 17:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 14 ber: Medical History Term: eye glass wearer Start Date: UNK/UNK/1982 Ongoing: YES	Initial Entry
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Ln Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 17:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 17:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: eye glass wearer	Initial Entry

Ln Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 17:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1982	Initial Entry

Ln Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 17:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1131

Subject No: 11311021

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
Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 169.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry
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6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33.9	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.7 Temperature Unit: C Temperature Location: ORAL C Temperature Location: AVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-17-2020 13:41:09 (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
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1131

Subject No: 11311021

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

Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry
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7.a Unit:

Date	Location	User	Value	Reason
Aug-17-2020 13:41:09 (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
Aug-17-2020 13:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1131

Subject No: 11311021

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
Aug-17-2020 13:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-17-2020 13:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 228819	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

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
Aug-17-2020 13:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 13:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 17:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 13:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 13:42:27	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Date of Collection: Aug/17/2020
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5.a

Date	Location	User	Value	Reason
Aug-17-2020 17:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6DG4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 17:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6DG4	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-17-2020 17:48:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6DG5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 17:48:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6DG5	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

5.c

Date	Location	User	Value	Reason
Aug-17-2020 17:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6DG6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 17:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6DG6	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-17-2020 17:48:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9VS6	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 17:48:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9VS6	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-17-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

17:48:55 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Sample ID: BL9VS7	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 17:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9VS7	Initial Entry

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: 11311021

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
Aug-17-2020 13:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 13:42:35 (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
Aug-17-2020 17:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 13:42:35 (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.
Aug-17-2020 13:42:35	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (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: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Date of Collection:	Aug/17/2020
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5.a

Date	Location	User	Value	Reason
Aug-17-2020 17:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6DTH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 17:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6DTH	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PRiMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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
Aug-17-2020 13:43:04 (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
Aug-17-2020 13:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-17-2020 13:43:04 (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
Aug-17-2020 13:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020 10:28	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Aug-17-2020 13:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Aug-17-2020 13:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-17-2020 13:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-17-2020 13:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERIO D	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1131

Subject No: 11311021

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
Aug-17-2020 13:43:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICIT Y E-DIARY NOT COLL ECTED FOR THIS SUBJ ECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-09-2020 11:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PRiMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Sep-09-2020 11:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 11:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature 36.6 : Temperature C Unit: Temperature ORAL C Location: AVITY	Transcription Error
Sep-09-2020 11:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature 36.6 : Temperature F Unit: Temperature ORAL C Location: AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Sep-09-2020 11:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 11:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-09-2020 11:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 36.6 F is outside of Normal Range 97 - 99.5 F.
Sep-09-2020 11:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 11:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Transcription Error
Sep-09-2020 11:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-09-2020 11:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: 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: 11311021

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-09-2020 11:00:38 (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-09-2020 11:00:38 (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-09-2020 19:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 11:00:38 (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-09-2020 11:00:38 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1131 **Site Name:** (1131) PriMED Clinical Research
Subject No: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Time (US & Canada)			Sep/9/2020	
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5.a

Date	Location	User	Value	Reason
Sep-09-2020 19:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6DZL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 19:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6DZL	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1131

Subject No: 11311021

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-09-2020 11:01:02 (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-09-2020 11:01:02 (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-09-2020 11:01:02 (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-09-2020 11:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 08:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 11:01:02	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	DELTOID MUSCLE	
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6. Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 11:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-09-2020 11:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-09-2020 11:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-09-2020 11:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-09-2020 17:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 17:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 18:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 17:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 17:25:33 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			Oct/9/2020	
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5.a

Date	Location	User	Value	Reason
Oct-09-2020 18:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP99TX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 18:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP99TX	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 18:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9VK3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 18:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9VK3	Initial Entry

5.c

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-09-2020 18:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BL9VK4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 18:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9VK4	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-09-2020 17:25:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-09-2020 17:25:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 17:25:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Mar-05-2021 17:27:04 (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: 11311021

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
Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

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
Mar-05-2021 17:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Incomplete, Not Verified
Site No: 1131 **Site Name:** (1131) PriMED Clinical Research
Subject No: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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1. Category:

Date	Location	User	Value	Reason
Mar-05-2021 17:27:04 (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
Mar-05-2021 17:27:04 (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
Mar-05-2021 17:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Deep Vein Thrombosis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 17:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/2/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Incomplete, Not Verified
Site No: 1131 **Site Name:** (1131) PriMED Clinical Research
Subject No: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Mar-05-2021 17:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-05-2021 17:27:04 (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
Mar-08-2021 04:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 17:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Deep Vein Thrombosis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-05-2021	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Not Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

<p>17:27:04 (UTC-05:00) Eastern Time (US & Canada)</p>		<p>(b) (4), (b) (6)</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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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
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Incomplete, Not Verified
Site No: 1131 **Site Name:** (1131) PriMED Clinical Research
Subject No: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Mar-05-2021 17:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-08-2021 15:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical: site to update when records available
Mar-08-2021 15:50:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we don't have hospital records yet data will be updated as soon as we received the information
Mar-08-2021 09:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: please confirm no risk factors such as recent trauma, surgery or prolonged immobility. Thanks
Mar-05-2021 17:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study t reatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Incomplete, Not Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

			Uncertain etiology	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 17:27:04 (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
Mar-09-2021 03:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candi date	Please update when data is available. Thank you.
Mar-08-2021 15:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we don't have hospital records yet data will be updated as soon as we received the information
Mar-08-2021 00:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Was a Concomitant Medication given?" is missing. Kindly review and update.

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Incomplete, Not Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Mar-09-2021 03:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candi date	Please update when data is available. Thank you.
Mar-08-2021 15:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we don't have hospital records yet data will be updated as soon as we received the information
Mar-08-2021 00:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Was a Non-Drug Treatment given?" is missing. Kindly review and update.

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

Date	Location	User	Value	Reason
Mar-05-2021 17:27:04 (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
Mar-05-2021 17:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 11311021

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Not Verified

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

Date	Location	User	Value	Reason
Mar-08-2021 04:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 2021247386	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1131

Subject No: 11311021

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Not Verified

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
Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-05-2021 17:28:41 (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
Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aortic Aneurysm	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/2/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Incomplete, Not Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-05-2021 17:28:41 (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
Mar-05-2021 17:28:41 (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
Mar-08-2021 04:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Aortic Aneurysm: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Incomplete, Not Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>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 persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO</p>	<p>Initial Entry</p>
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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
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090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Incomplete, Not Verified
Site No: 1131 **Site Name:** (1131) PriMED Clinical Research
Subject No: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 15:11:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-08-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we don't have hospital records yet data will be updated as soon as we received the information
Mar-08-2021 15:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Causality of Aortic Aneurysm is reported as HTN. Subject's MH reports HTN ended in 2015. Please determine if AE of Hypertension should be recorded and update as needed.
Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study t reatment(s), this event i s due to:	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Incomplete, Not Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

			OTHER	
			<i>If Other, specify:</i>	
			Hypertension	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 17:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-10-2021 14:16:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Cand idate	Wait for missing information to be added for this AE until after 15MAR2021
Mar-10-2021 10:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	march152021
Mar-10-2021 04:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open ed	DM2: Please confirm next visit due for subject.
Mar-09-2021 14:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we can not give you tentative date to update details, we have

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Incomplete, Not Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Canada)				requested for the hospital records and will update details as soon as we get it
Mar-09-2021 04:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Please let us know tentative date by when you will be able to update the details. Thank you.
Mar-08-2021 15:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we don't have hospital records yet data will be updated as soon as we received the information
Mar-08-2021 00:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Was a Concomitant Medication given?" is missing. Kindly review and update.

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 14:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Candidate query was added for one of the missing fields instead of three candidate queries

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Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Incomplete, Not Verified
Site No: 1131 **Site Name:** (1131) PriMED Clinical Research
Subject No: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Mar-10-2021 10:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	march152021
Mar-10-2021 04:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open ed	DM2: Please confirm next visit date subject is due with.
Mar-09-2021 14:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we can not give you tentative date to update details, we have requested for the hospital records and will update details as soon as we get it
Mar-09-2021 04:19:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Open ed	DM1: Please let us know tentative date by when you will be able to update the details. Thank you.
Mar-08-2021 15:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we don't have hospital records yet data will be updated as soon as we received the information
Mar-08-2021 00:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Was a Non-Drug Treatment

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Incomplete, Not Verified
Site No: 1131 **Site Name:** (1131) PriMED Clinical Research
Subject No: 11311021 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

				given?" is missing. Kindly review and update.
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-05-2021 17:28:41 (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
Mar-05-2021 17:28:41 (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
Mar-08-2021 04:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021247386	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Incomplete, Not Verified

Site No: 1131

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Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Mar-05-2021 17:29:52 (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
Mar-05-2021 17:29:52 (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
Mar-05-2021 17:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pulmonary Embolism	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 17:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/2/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

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Form Status: Incomplete, Not Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Mar-05-2021 17:29:52 (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
Mar-05-2021 17:29:52 (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
Mar-08-2021 04:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 17:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pulmonary Embolism: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Incomplete, Not Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

<p>Mar-05-2021 17:29:52 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>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 persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO</p>	<p>Initial Entry</p>
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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
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Incomplete, Not Verified

Site No: 1131

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Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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Mar-05-2021 17:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 17:29:52 (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> Deep vein thrombosis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 17:29:52 (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
Mar-10-2021 05:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candi date	Please update when data is available. Thank you.
Mar-09-2021	ACV0PFEINFP6000	(b) (6)	Query 1: Answered	we can not give

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Incomplete, Not Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311021**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

14:55:59 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		you tentative date to update details, we have requested for the hospital records and will update details as soon as we get it
Mar-09-2021 04:18:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM1: Please let us know tentative date by when you will be able to update the details. Thank you.
Mar-08-2021 15:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we don't have hospital records yet data will be updated as soon as we received the information
Mar-08-2021 00:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Was a Concomitant Medication given?" is missing. Kindly review and update.

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 14:22:05 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Candidate query was added for one of the

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1131**Subject No:** 11311021**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Incomplete, Not Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				missing fields instead of three candidate queries
Mar-09-2021 14:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we can not give you tentative date to update details, we have requested for the hospital records and will update details as soon as we get it
Mar-09-2021 04:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Please let us know tentative date by when you will be able to update the details. Thank you.
Mar-08-2021 15:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we don't have hospital records yet data will be updated as soon as we received the information
Mar-08-2021 00:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Was a Non-Drug Treatment given?" is missing. Kindly review and update.

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

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Subject No: 11311021

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Not Verified

Site Name: (1131) PriMED Clinical Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-05-2021 17:29:52 (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
Mar-05-2021 17:29:52 (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
Mar-08-2021 04:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021247386	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 09:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-29-2021 09:33:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-29-2021 09:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-29-2021 09:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY F OR ADDITIONAL VACC INATION	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1131

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Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Oct-09-2020 17:25:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-17-2020 13:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZE D	Initial Entry
Aug-17-2020 13:30:53 (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
Mar-13-2021 00:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	entry erroneous
Mar-12-2021 11:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	e-diary entry considered erroneous
Mar-12-2021 00:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Response states 'subject was in a hospital for surgery'. Please confirm if

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

				Illness ed diary entry of 08MAR2021 was deemed erroneous and that subject had no Covid Illness symptoms. Else clarify.
Mar-11-2021 14:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject was in a hospital for surgery
Mar-11-2021 13:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 08MAR2021. But there is no COVID Illness visit reported in the database. Please clarify
Oct-09-2020 17:25:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/9/2020	Initial Entry
Aug-17-2020 13:41:36	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

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Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)				
Aug-17-2020 13:30:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae3ea2\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311021

Subject Initials: ---

Generated By: (b) (4)

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-16-2020 09:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry