

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** 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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/11/2021
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11311301]
2.	Birth Date:	(b) (6) /2007
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 Version:** 22-Apr-2020 21:02

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** DISPOSITION - SCREENING

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Jan/11/2021
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL 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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[allergic rhinitis seasonal]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[attention deficit hyperactivity disorder]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[adenoids removed]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL 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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[fall off diving board]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[stiches insertion back of head]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015

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**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** HIV STATUS

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	--	---

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jan/11/2021
2.	Weight:	[45.5]
3.	Unit:	kg
4.	Height:	[161.2]
5.	Unit:	cm
6.	Body Mass Index:	[17.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Jan/11/2021
2.	Randomization Number:	[26309]
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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR0F75]
5.b	Sample ID	[BR0F76]
5.c	Sample ID	[BS7XR6]

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9B98]
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**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/11/2021 14:50
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

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**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/5/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Feb/5/2021
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.9]
	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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR0G7Y]
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[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:	Feb/5/2021 14:06
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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/12/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**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:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BTZPYP]
5.b	Sample ID	[BTZPYR]
5.c	Sample ID	[BS2DVM]

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/9/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BTZR49]
5.b	Sample ID	[BTZR4B]
5.c	Sample ID	[BVTP0G]

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**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	[ ]
----	-----------	-----

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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 Version:** 30-Apr-2021 01:47

**Site No:** 1131

**Subject No:** 11311301

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:	[ ]
----	------------------------	-----

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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	[ ]
----	-----------	-----

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

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

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**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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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

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

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11311301    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 10-Nov-2021 20:44

**Unplanned Assessments**

1.	Assessments	
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**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Vital Signs**

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

**Vital Signs Details**

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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?	

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Contact Outcome**

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

**Header Text:** c4591001

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

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

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/25/2021
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:** Data Complete, Frozen, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/25/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -  
Unscheduled IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR0F92]
5.b	Sample ID	[BR0F93]
5.c	Sample ID	[BS7XVM]

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9BC5]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/05/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/5/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/05/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/22/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/22/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/22/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR0GDF]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/12/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/12/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK6
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/12/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR8XB]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/24/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK8
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/24/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR8Z1]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/07/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Apr/7/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK10
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/07/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Apr/7/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR90L]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on Apr/20/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Apr/20/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK12
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on Apr/20/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Apr/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR91J]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/04/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Date of Visit**

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

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK14
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/04/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR92H]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 8 -  
Unscheduled Visit on May/19/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Date of Visit**

1.	Date of Visit	May/19/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK16
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 8 -  
Unscheduled Visit on May/19/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: May/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR93J]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 9 -  
Unscheduled Visit on Jun/01/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Date of Visit**

1.	Date of Visit	Jun/1/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK18
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 9 -  
Unscheduled Visit on Jun/01/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR941]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 10 -  
Unscheduled Visit on Jun/11/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Date of Visit**

1.	Date of Visit	Jun/11/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK20
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 10 -  
Unscheduled Visit on Jun/11/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jun/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR94M]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 11 -  
Unscheduled Visit on Jun/22/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Date of Visit**

1.	Date of Visit	Jun/22/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK22
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 11 -  
Unscheduled Visit on Jun/22/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jun/22/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR958]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 12 -  
Unscheduled Visit on Jul/06/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Date of Visit**

1.	Date of Visit	Jul/6/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK24
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 12 -  
Unscheduled Visit on Jul/06/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jul/6/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR95M]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 13 -  
Unscheduled Visit on Aug/09/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Date of Visit**

1.	Date of Visit	Aug/9/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK26
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 13 -  
Unscheduled Visit on Aug/09/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRR966]
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**Header Text:** c4591001

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

**Form Version:** 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Mar/12/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

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

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

**Subject No:** 11311301      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen

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

**Subject No:** 11311301      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 10-Nov-2021 20:44

[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
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**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Disposition - Follow-Up**

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

**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	sacroiliac joint pain	Jan/15/2021 UNK:UNK	NO End Date Time:  Feb/8/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2. DELETED	ADVERSE EVENT	2	broken collar bone	Feb/19/2021 UNK:UNK	NO End Date Time:  Apr/23/2021 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	right clavicle fracture	Feb/19/2021 11:00	NO End Date Time:  Apr/23/2021 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	skiing accident	Feb/18/2021 11:00	NO End Date Time:  Feb/19/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[sacroiliac joint pain]
4.	Start Date Time:	Jan/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/8/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Deleted

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ <del>broken collar bone</del> ]
4.	Start Date Time:	<del>Feb/19/2021 UNK:UNK</del>
5.	Is the adverse event still ongoing?	<del>NO</del> <del>End Date Time:</del> <del>Apr/23/2021 UNK:UNK</del>
6.	Toxicity Grade:	‡

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Deleted

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Deleted

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[right clavicle fracture]
4.	Start Date Time:	Feb/19/2021 11:00
5.	Is the adverse event still ongoing?	NO End Date Time: Apr/23/2021 UNK:UNK
6.	Toxicity Grade:	2

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[skiing accident]
4.	Start Date Time:	Feb/18/2021 11:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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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	[ ]

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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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:	//

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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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?	

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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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?	

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** UNPLANNED\_BOOSTER\_CONTACT  
- Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:**  
UNPLANNED\_BOOSTER\_CONTACT  
- Unscheduled

**Form:** BOOSTER DOSE TRIGGER FORM

**Form Version:** 13-Apr-2021 01:26

**Form Status:** Not Started

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Booster Dose Trigger Form**

- |    |  |  |
|----|--|--|
| 1. | Select appropriate response<br>- Will the participant return<br>for consent/eligibility<br>assessment for the booster<br>dose visit? |  |
|----|--|--|

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	May/18/2021
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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Mar/12/2021

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[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, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

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

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Jan-11-2021 16:37:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6) [Redacted]	N/A	Aug-09-2021 12:20:22 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

William Randall	Approved	Jul-23-2021 13:49:50 (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) [Redacted]	N/A	Mar-25-2021 15:09:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Affidavit:**

N/A

William Randall	Approved	Mar-23-2021 18:56:25 (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.

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Jan-11-2021 16:36:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 16:36:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Consent Was:*

Date	Location	User	Value	Reason
Jan-11-2021 16:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/11/2021	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

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**1. Subject ID**

Date	Location	User	Value	Reason
Jan-11-2021 16:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 11311301	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Jan-11-2021 16:35:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /2007	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Jan-15-2021 01:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Jan-14-2021 15:58:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Query 1: Answered	dcf has been submitted to impala
Jan-13-2021 01:54:42	ACV0PF EINFP60	(b) (4), (b) (6) [Redacted]	Query 1: Opened	IVRS Reconciliation:

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		There is a mismatch between the sex reported in InForm (Male) and the sex report in IMPALA (Female). Please review and reconcile.
Jan-11-2021 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Jan-11-2021 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

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***1. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-13-2021 03:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-12-2021 09:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	data updated
Jan-12-2021 05:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	DM: Please update all the missing pages under this visit or else clarify. Thank you.
Jan-11-2021 16:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-11-2021 16:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-11-2021 16:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-11-2021 16:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Jan-12-2021 09:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> allergic rhinitis seasonal <b>Start Date:</b> UNK/UNK/2014 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 09:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 09:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> allergic rhinitis seasonal	Initial Entry

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

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: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-12-2021 09:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Jan-12-2021 09:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Jan-12-2021 09:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 2 <b>Number:</b> <b>Medical History Term:</b> attention deficit hyperactivity disorder <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-12-2021 09:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 09:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> attention deficit hyperactivity disorder	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Jan-12-2021 09:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Jan-12-2021 09:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-12-2021 09:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 3 <b>mber:</b> <b>Medical Histo</b> adenoids rem <b>ry Term:</b> oved <b>Start Date:</b> UNK/UNK/2 015 <b>Ongoing:</b> NO End Date:  UNK/UN K/2015	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-12-2021 09:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 09:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> adenoids removed	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 09:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.c Ongoing:***

Date	Location	User	Value	Reason
Jan-12-2021 09:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2015	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

*1.d*

Date	Location	User	Value	Reason
Jan-12-2021 14:12:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Nu</b> 4 <b>mber:</b> <b>Medical Hist</b> fall off divin <b>ory Term:</b> g board <b>Start Date:</b> UNK/UNK/ 2015 <b>Ongoing:</b> NO End Date:  UNK/UN K/2015	New Information
Jan-12-2021 09:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 4 <b>H Numb</b> <b>er:</b> <b>Medical</b> fall off diving bo <b>History</b> ard, stiches back <b>Term:</b> of head <b>Start Da</b> UNK/UNK/201 <b>te:</b> 5 <b>Ongoing</b> NO : End Date:  UNK/UNK/2 015	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-12-2021 09:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Jan-12-2021 14:12:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
Jan-12-2021 14:12:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> fall off diving board	New Information
Jan-12-2021 14:04:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term FALL OFF DIVING BOARD,

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

	ancy			STICHES BACK OF HEAD. Split the term into FALL OFF DIVING BOARD and STICHES INSERTION BACK OF HEAD and submit separately. Thank you.
Jan-12-2021 09:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> fall off diving board, stiches back of head	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Jan-12-2021 09:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Jan-12-2021 09:28:53	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)	End Date:  UNK/UNK/2015
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*I.e*

Date	Location	User	Value	Reason
Jan-12-2021 14:15:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N umber:</b> 5 <b>Medical History Term:</b> stitches insertion back of head <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> NO End Date:  UNK/UNK/2015	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*1.e Line/MH Number:*

Date	Location	User	Value	Reason
Jan-12-2021 14:15:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 14:15:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> stiches insertion back of head	Initial Entry

*1.e Start Date:*

Date	Location	User	Value	Reason
Jan-12-2021 14:15:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

*1.e Ongoing:*

Date	Location	User	Value	Reason
Jan-12-2021 14:15:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2015	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** HIV STATUS - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-12-2021 09:29:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date:**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 45.5	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> 161.2	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		
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5. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 17.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature: 36.9</b> <b>Temperature U C nit:</b> <b>Temperature L ORAL CA location:: VITY</b>	Initial Entry

7.a Record Identifier:

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 36.9	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Jan-12-2021 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 26309	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 17:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Jan-11-2021 17:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/11/2021	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR0F75	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR0F75	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR0F76	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR0F76	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS7XR6	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 17:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BS7XR6	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 17:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-11-2021 17:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-11-2021 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 17:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Jan-11-2021 17:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/11/2021	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Jan-11-2021 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9B98	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BP9B98	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021 14:50	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE D 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
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Jan-12-2021 09:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b><u>Data Entry:</u></b> YES	Initial Entry
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Jan-12-2021 09:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED F OR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-09-2021 04:52:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation_PD tracker updated
Feb-09-2021 03:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-08-2021 12:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	date is correct, subject and family were out of town for 2 weeks which fell during visit 2 window
Feb-08-2021 12:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	the date is correct, subject and family were out of town for 2 weeks which fell during visit 2 window
Feb-08-2021 05:09:52 (UTC-05:00) Eastern Time	ACV0PF EINFP60 00.InFormAdapte	DMW QUERY (b) (4)	Query 2: Opened	DMW7171251;The Date of Visit at Visit 'V2_VAX2_L' is not in chronological

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(US & Canada)	r.Discrepancy			order based on the visit schedule. Please review and update as appropriate.
Feb-08-2021 01:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFormAdapt r.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V2_VAX2_L is out of window for 2 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Feb-05-2021 16:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V E R  <b>Were fever or systemi N</b> <b>c symptoms present o O</b> <b>n the last day the Subj</b> <b>ect Diary was complet</b> <b>ed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Time (US & Canada)

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or system ic symptoms present on the last day the S ubject Diary was co mpleted?:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or systemi</b> N <b>c symptoms present o</b> O <b>n the last day the Sub</b> <b>ject Diary was comple</b> <b>ted?:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G <b>Were fever or system ic symptoms present on the last day the S ubject Diary was co mpleted?:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED MUSCL E PAIN  <b>Were fever or sy NO</b> <b>stemic symptoms</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER M USCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENER JOINT PAIN  <b>Were fever or sys NO temic symptoms present on the las t day the Subject Diary was compl eted?:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.h Symptom:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.a

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE DN ES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 17:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date:**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature: 36.9</b> <b>Temperature U C</b> <b>nit:</b> <b>Temperature L ORAL CA</b> <b>ocation:: VITY</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Feb-05-2021 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 36.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Feb-05-2021 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 16:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 16:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-05-2021 16:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 16:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Feb-05-2021 16:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-05-2021 16:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR0G7Y	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 16:45:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR0G7Y	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1131

**Subject No:** 11311301

**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):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021 14:06	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Feb-05-2021 17:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b><u>Data Entry:</u></b> YES	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-15-2021 13:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-15-2021 13:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-15-2021 09:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	data updated
Mar-15-2021 09:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	data updated
Mar-15-2021 06:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Mar-15-2021 06:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: Kindly consider to update missing SYMPRDATE form or else clarify. Thank you.
Mar-12-2021 15:47:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Mar/12/2021	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V E R  <b>Were fever or systemi N</b> <b>c symptoms present o O</b> <b>n the last day the Subj</b> <b>ect Diary was complet</b> <b>ed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or system ic symptoms present on the last day the S ubject Diary was co mpleted?:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or systemi</b> N <b>c symptoms present o</b> O <b>n the last day the Sub</b> <b>ject Diary was comple</b> <b>ted?:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G <b>Were fever or system ic symptoms present on the last day the S ubject Diary was co mpleted?:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENE MUSCL E PAIN  <b>Were fever or sy NO</b> <b>stemic symptoms</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER M USCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENER JOINT PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.h Symptom:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.a

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE DN ES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 09:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-12-2021 15:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-12-2021 15:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-12-2021 15:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 15:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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: 11311301 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Mar-12-2021 15:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 15:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BTZPYP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 15:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZPYP	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-12-2021 15:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BTZPYR	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-12-2021 15:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZPYR	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-12-2021 15:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS2DVM	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-12-2021 15:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BS2DVM	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-09-2021 12:26:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/9/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-09-2021 12:28:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-09-2021 12:28:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-26-2021 11:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Sent to ICON for assistance resolving issue
Aug-25-2021 12:40:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	Updated

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Aug-25-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Opened	LIMS2: Thank you for the response. Please enter the barcode under Sample ID below.
Aug-25-2021 09:56:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	BTZR48 belongs to subject 11311301 and visit 4 09AUG2021
Aug-24-2021 10:08:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Opened	LIMS1: The lab did receive BTZR48 as well. Please clarify if BTZR48 belongs to another subject or visit. Otherwise please clarify.
Aug-23-2021 11:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	Wrong bar code was listed at first ,updated to proper bar code
Aug-23-2021 10:55:24	ACV0PF EINFP60	(b) (4), (b) (6)	Query 2: Opened	LIMS: For Visit 5, the lab

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		received serum sample barcode BTZR48; however, it has been deleted below. All samples collected and sent to the lab (SEND and RETAIN samples) must be recorded. Please review and update as appropriate.
Aug-09-2021 12:28:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-09-2021 12:28:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-09-2021 12:28:28 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Eastern Time (US & Canada)		(b) (4), (b) (6)	Aug/9/2021	
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5.a

Date	Location	User	Value	Reason
Aug-09-2021 12:28:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTZR49</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-09-2021 12:28:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZR49	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-20-2021 11:18:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTZR4B</b>	Changed Information
Aug-09-2021 12:29:17 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTZR48</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Eastern Time (US & Canada)		(b) (4), (b) (6)		
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Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Sample ID

Date	Location	User	Value	Reason
Aug-23-2021 10:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-23-2021 10:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	LIMS: For Visit 4, the lab received BTZR48; however, BTZR4B is recorded. Please review for possible data entry error and correct if appropriate. Otherwise please clarify.
Aug-20-2021 11:18:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZR4B	Changed Information
Aug-09-2021 12:29:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZR48	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.c**

Date	Location	User	Value	Reason
Aug-09-2021 12:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BVTP0G	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-09-2021 12:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BVTP0G	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-26-2021 09:15:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Consent Was:*

Date	Location	User	Value	Reason
Jan-26-2021 09:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obt ained  Jan/25/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-26-2021 09:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-26-2021 09:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-27-2021 08:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 09:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jan-26-2021 09:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/25/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-27-2021 08:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR0F92	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-27-2021 08:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR0F92	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-27-2021 08:41:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR0F93	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-27-2021 08:41:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR0F93	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-27-2021 08:41:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS7XVM	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-27-2021 08:41:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BS7XVM	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
Unscheduled SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-26-2021 09:16:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-26-2021 09:16:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-27-2021 07:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 09:16:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
Unscheduled SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jan-26-2021 09:16:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/25/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-27-2021 07:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9BC5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-27-2021 07:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BP9BC5	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-05-2021 16:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Feb-05-2021 16:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK2	Initial Entry

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/05/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 16:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 16:46:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-05-2021 16:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

16:46:22 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Sample was taken for Visit 2 which was done at same visit
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/22/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-22-2021 11:38:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/22/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Feb-22-2021 11:38:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK4	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/22/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-22-2021 11:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-22-2021 11:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-22-2021 12:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 11:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/22/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Feb-22-2021 11:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/22/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-22-2021 12:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR0GDF	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-22-2021 12:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR0GDF	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/12/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-16-2021 08:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-15-2021 09:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	dates are correct
Mar-15-2021 03:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7698441;The Date of Visit at Visit at Visit 'COVID-19 Surveillance Visit = SSWAB_WEEK6' is the same as the other Date of Visit at Visit 'V3POSTVX2L'. Please review for duplication and update as appropriate.

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/12/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

Mar-12-2021 15:19:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/12/2021	Initial Entry
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**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Mar-12-2021 15:19:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK6	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/12/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-12-2021 15:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-12-2021 15:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-12-2021 15:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 15:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/12/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Mar-12-2021 15:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/12/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-12-2021 15:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRR8XB</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-12-2021 15:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR8XB	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-25-2021 15:09:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/24/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Mar-25-2021 15:09:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK8	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-25-2021 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-25-2021 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-25-2021 15:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-25-2021 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Mar-25-2021 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-25-2021 15:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR8Z1	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-25-2021 15:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR8Z1	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/07/2021

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

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Apr-07-2021 13:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/7/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-07-2021 13:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK10	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/07/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-07-2021 13:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-07-2021 13:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-07-2021 15:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-07-2021 13:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/07/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Apr-07-2021 13:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/7/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-07-2021 15:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR90L	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-07-2021 15:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR90L	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on Apr/20/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Apr-20-2021 12:58:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/20/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-20-2021 12:58:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK12	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on Apr/20/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-20-2021 12:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-20-2021 12:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-21-2021 08:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-20-2021 12:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on Apr/20/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Apr-20-2021 12:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/20/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-21-2021 08:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR91J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-21-2021 08:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR91J	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/04/2021

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

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
May-04-2021 12:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/4/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
May-04-2021 12:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK14	Initial Entry

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/04/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-04-2021 12:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-04-2021 12:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-04-2021 16:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-04-2021 12:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/04/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
May-04-2021 12:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  May/4/2021	Initial Entry

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

Date	Location	User	Value	Reason
May-04-2021 16:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-04-2021 16:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR92H	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-04-2021 16:40:58 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR92H	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/04/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Time (US & Canada)				
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 8 -  
Unscheduled Visit on May/19/2021

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

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
May-19-2021 14:07:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/19/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
May-19-2021 14:07:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK16	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 8 -  
Unscheduled Visit on May/19/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-19-2021 14:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-19-2021 14:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-19-2021 16:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-19-2021 14:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 8 -  
Unscheduled Visit on May/19/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
May-19-2021 14:08:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  May/19/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-19-2021 16:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR93J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-19-2021 16:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR93J	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 9 -  
Unscheduled Visit on Jun/01/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1131

**Subject No:** 11311301

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jun-01-2021 12:19:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/1/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Jun-01-2021 12:19:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK18	Initial Entry

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 9 -  
Unscheduled Visit on Jun/01/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jun-01-2021 12:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jun-01-2021 12:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jun-01-2021 16:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-01-2021 12:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 9 -  
Unscheduled Visit on Jun/01/2021

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

**Site No:** 1131

**Subject No:** 11311301

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jun-01-2021 12:19:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jun/1/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jun-01-2021 16:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR941	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jun-01-2021 16:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR941	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 10 -  
Unscheduled Visit on Jun/11/2021

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

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jun-11-2021 11:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/11/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Jun-11-2021 11:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK20	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 10 -  
Unscheduled Visit on Jun/11/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jun-11-2021 11:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jun-11-2021 11:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jun-11-2021 11:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-11-2021 11:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 10 -  
Unscheduled Visit on Jun/11/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jun-11-2021 11:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jun/11/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jun-11-2021 11:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR94M	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jun-11-2021 11:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR94M	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 11 -  
Unscheduled Visit on Jun/22/2021

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

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jun-23-2021 10:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/22/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Jun-23-2021 10:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK22	Initial Entry

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 11 -  
Unscheduled Visit on Jun/22/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jun-23-2021 10:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jun-23-2021 10:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jun-24-2021 09:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jun-23-2021 15:10:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 11 -  
Unscheduled Visit on Jun/22/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311301**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Jun-23-2021 10:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jun-23-2021 10:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jun/22/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jun-24-2021 09:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR958	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jun-24-2021 09:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR958	Initial Entry

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 12 -  
Unscheduled Visit on Jul/06/2021

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

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jul-06-2021 13:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/6/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Jul-06-2021 13:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK24	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 12 -  
Unscheduled Visit on Jul/06/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jul-06-2021 13:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jul-06-2021 13:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jul-06-2021 13:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-06-2021 13:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 12 -  
Unscheduled Visit on Jul/06/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Jul-06-2021 13:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jul/6/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jul-06-2021 13:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRR95M</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jul-06-2021 13:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR95M	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 13 -  
Unscheduled Visit on Aug/09/2021

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

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-12-2021 01:45:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Aug-11-2021 08:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Subject went out of town
Aug-11-2021 00:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at SSWAB_WEEK26 is out of window for 16 days from SSWAB_WEEK24 DOV. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Aug-09-2021 12:20:21 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/9/2021	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 13 -  
Unscheduled Visit on Aug/09/2021

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

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Eastern Time (US & Canada)				
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**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Aug-09-2021 12:20:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> SSWAB_WEEK26	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 13 -  
Unscheduled Visit on Aug/09/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-09-2021 12:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-09-2021 12:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-09-2021 12:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-09-2021 12:22:22 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 13 -  
Unscheduled Visit on Aug/09/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Canada)				entered. Please review and correct as appropriate.
Aug-09-2021 12:22:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-09-2021 12:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRR966	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-09-2021 12:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRR966	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Mar-15-2021 09:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/12/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-15-2021 09:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-15-2021 09:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

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

**Subject No:** 11311301      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
May-18-2021 14:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/18/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

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

**Subject No:** 11311301 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
May-18-2021 14:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 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

**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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

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Date	Location	User	Value	Reason
May-04-2021 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (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:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (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:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Category:**

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> sacroiliac joint pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021 UNK:UNK	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Apr-20-2021 13:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/8/2021 UNK:UNK	New Information
Feb-22-2021 14:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 12:09:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	yes it is still ONGOING
Feb-22-2021 10:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - SACROLLIAC JOINT PAIN (15 Jan 21) related to Excess Exercise is still reported as ONGOING. Please confirm or enter END DATE if known.

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  excess exercise	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-05-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

17:43:51 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	NO	
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Apr-20-2021 13:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVE D	New Information
Feb-05-2021 17:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-05-2021 17:43:51 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Time (US & Canada)				
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**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

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

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**1. Category:**

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> broken collar bone	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Deleted

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

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

Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/19/2021 UNK:UNK	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
May-05-2021 10:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Duplicate to AE 3
May-04-2021 12:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
May-04-2021 12:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Apr/23/2021 UNK:UN K	New Information
May-04-2021 10:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - BROKEN COLLAR BONE (19 Feb 21) is still reported as

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

				ONGOING. Please confirm AE is ongoing, or enter END DATE as applicable.
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
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Header Text: c4591001

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Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**8. Is this adverse event the result of a study Medication Error?**

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

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  injury	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
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Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
May-04-2021 12:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
May-04-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information

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**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

12:41:49 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	RECOVERED/RESOLVED	
May-04-2021 12:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	For AE broken collar bone: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-16-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

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**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Category:**

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> right clavicle fracture	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-16-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

15:14:21 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Feb/19/2021 11:00	
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
May-05-2021 10:47:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (4), (b) (6)	Query 1: Closed	Response satisfies query
May-04-2021 12:40:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
May-04-2021 12:40:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Apr/23/2021 UNK:UN K	New Information
May-04-2021 10:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (4), (b) (6)	Query 1: Opened	CLINQUERY - Right CLAVICLE FRACTURE (19 Feb 21) is still reported as ONGOING. Please confirm AE is ongoing,

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Generated By: (b) (4)

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				or enter END DATE as applicable.
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-23-2021 04:05:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-22-2021 14:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	data updated per query
Mar-22-2021 13:49:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:O pened	Skiing accident should be entered as a separate event on the Logs, ADVERSE EVENT REPORT page.
Mar-22-2021	ACV0PF	(b) (4), (b) (6)	Query 1: Answered	could you please

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**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

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11:00:41 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)		clarify which appropriate page should we capture this data
Mar-19-2021 12:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [skiing accident]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

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Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				skiing accident
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
May-04-2021 12:40:54	ACV0PF EINFP60	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
May-04-2021 12:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOL VED	New Information
May-04-2021 12:40:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	For AE right clavicle fracture: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESO LVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-16-2021 15:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

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

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**1. Category:**

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> skiing accident	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-22-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

14:56:31 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Feb/18/2021 11:00	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Apr-01-2021 12:05:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-31-2021 15:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
Mar-31-2021 15:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/19/2021 UNK:UNK	New Information
Mar-31-2021 10:29:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (4), (b) (6)	Query 1: Opened	CLINQUERY - SKIING ACCIDENT is reported as ONGOING. However, as an accident, the Start and Stop dates are expected to be

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				the same. Please review and update as appropriate.
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311301

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-31-2021 15:04:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-31-2021 15:04:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOL VED	New Information
Mar-31-2021 15:03:32	ACV0PF EINFP60	auto query (autoquery)	Query 1: Opened	For AE skiing accident: Response to

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			"What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-22-2021 14:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
May-18-2021 14:21:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/18/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
May-18-2021 14:21:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Subject Status**

Date	Location	User	Value	Reason
Mar-15-2021 09:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Jan-12-2021 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Jan-11-2021 16:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-15-2021 09:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Mar/12/2021	Initial Entry
Jan-12-2021 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Jan/11/2021	Initial Entry
Jan-11-2021 16:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

090177e19891a040\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

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

**Subject No:** 11311301

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Mar-23-2021 12:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry