

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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	06 OCT 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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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 Dec/3/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10071499]
2.	Birth Date:	(b) (6)/2006
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:	

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** DATE OF VISIT

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Dec/3/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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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090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

**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:	[Drug allergy Amoxicillin]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** HIV STATUS

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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-Oct-2020 16:04

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Dec/3/2020
2.	Weight:	[50.9]
3.	Unit:	kg
4.	Height:	[170.0]
5.	Unit:	cm
6.	Body Mass Index:	[17.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.6]
	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:** 1007

**Subject No:** 10071499

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

**Form:** RANDOMIZATION

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Dec/3/2020
2.	Randomization Number:	[20753]
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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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: Dec/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP90K9]
5.b	Sample ID	[BP90KB]
5.c	Sample ID	[BMRWDL]

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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: Dec/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP90K6]
-----	-----------	----------

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** VACCINATION

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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:	Dec/3/2020 16:21
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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	Dec/22/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

**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?	YES Ongoing? NO Stop Date: Dec/10/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Dec/22/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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: Dec/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP910N]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** VACCINATION

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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:	Dec/22/2020 15:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **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/20/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **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 WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **Subject Initials:** ---

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

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071499**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/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	[BRB8RY]
5.b	Sample ID	[BRB8RZ]
5.c	Sample ID	[BNWMPX]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** DATE OF VISIT

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jun/28/2021
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, Frozen, Verified

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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: Jun/28/2021
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	[BTDN2D]
5.b	Sample ID	[BTDN2F]
5.c	Sample ID	[BS0WKN]

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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:** 1007

**Subject No:** 10071499

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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	[ ]
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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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	[ ]
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**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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:	
----	-------------------------	--

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19**Form Version:** 30-Apr-2021 01:47**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071499**Subject Initials:** ---**Generated By:** (b) (4)**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:	[ ]
----	------------------------	-----

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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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090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

<b>Header Text:</b> c4591001	
<b>Visit:</b> POT_COVID_ILL - New Unscheduled Visit	<b>Form:</b> ELECTRONIC SAMPLE TRACKING - NASAL SWAB
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Form Status:</b> Not Started
<b>Site No:</b> 1007	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Subject No:</b> 10071499	<b>Subject Initials:</b> ---
<b>Generated By:</b> (b) (4)	<b>Generated Time (GMT):</b> 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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**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

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

**Health Care Utilization**

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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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:	
----	-------------------------	--

**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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071499**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	[ ]
----	-----------	-----



**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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:	
----	-----------------------	--

**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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071499**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	[ ]
----	-----------	-----

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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:** 1007    **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499    **Subject Initials:** ---

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

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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:	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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?	

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**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **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/18/2021
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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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 Mar/18/2021
----	--------------	--

**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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071499**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/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BV03D7]
5.b	Sample ID	[BV03D8]
5.c	Sample ID	[BS2895]

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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: Mar/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BV03D5]
<del>5.b</del>	Sample ID	[ <del>BV03D8</del> ]

**Header Text:** c4591001

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Jan/20/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/01/2021

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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/1/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	---------------------------------	-------------

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/01/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1007**Subject No:** 10071499**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**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_SELF
3.	Sample Collected?	YES Date of Collection: Apr/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	[AA02045]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/15/2021

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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/15/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
----	---------------------------------	-------------

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/15/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1007**Subject No:** 10071499**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**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_SELF
3.	Sample Collected?	YES Date of Collection: Apr/15/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[AA03045]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/29/2021

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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	Apr/29/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK6
----	---------------------------------	-------------

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/29/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1007**Subject No:** 10071499**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**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_SELF
3.	Sample Collected?	YES Date of Collection: Apr/29/2021
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	[AA03047]
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**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:** 1007      **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499      **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	May/4/2021
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, Verified

**Site No:** 1007      **Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499      **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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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	left wrist pain	May/1/2021 UNK:UNK	NO End Date Time:  May/3/2021 UNK: UNK	<a href="#">Repeating Pages</a>

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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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

**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:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[left wrist pain]
4.	Start Date Time:	May/1/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: May/3/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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: [Trauma]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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	[ ]

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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	[ ]

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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.	1	VACCINATIONS	NO	SARS-CoV-2 vaccination Pfizer	May/13/2021	<a href="#">Repeating Pages</a>
2.	2	VACCINATIONS	NO	SARS-CoV-2 mRNA vaccine Pfizer	Jun/4/2021	<a href="#">Repeating Pages</a>

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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[Form Audit Trail](#)

**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[SARS-CoV-2 vaccination Pfizer]
5.	Date:	May/13/2021

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[SARS-CoV-2 mRNA vaccine Pfizer]
5.	Date:	Jun/4/2021

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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>

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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?	

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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?	

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital  
Medical Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital  
Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

**Booster Dose Trigger Form**

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



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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/12/2021
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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** DATE OF VISIT

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER  
VACCINATION

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

**Form Status:** Not Started

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

**Informed Consent - Further Vaccination**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 28-Mar-2021 02:25

**Form Status:** Not Started

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	
----	--	--

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	
----	--	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

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

**Form Status:** Not Started

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

**Disposition - Screening for Further Vaccination**

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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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	Jan/20/2021



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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, Signed, Verified

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Aug-27-2021 11:14:24 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, RobertFrenck, 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.

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Dec-03-2020 16:10:55 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT - Comments

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Jun-29-2021 13:21:55 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT - Comments

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Jun-29-2021 13:21:55 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT - Comments

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Jun-29-2021 13:21:55 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Aug-27-2021 11:14:24 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, RobertFrenck, 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	Apr-01-2021 09:19:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Robert Frenck	Approved	Mar-19-2021 14:54:30 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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, Signed, Verified

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

**Affidavit:**

By my dated signature below, I, RobertFrenck, 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.

Haley Muth	N/A	Mar-18-2021 09:35:22 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Robert Frenck	Approved	Mar-16-2021 22:22:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

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

**Affidavit:**

By my dated signature below, I, RobertFrenck, 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.

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Dec-03-2020 16:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 16:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Dec-03-2020 16:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Dec/3/2020	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Dec-03-2020 16:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 10071499	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-03-2020 16:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/2006	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Dec-03-2020 16:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Dec-03-2020 16:10:32	ACV0PF EINFP60	Laura Pace	<b>Data Entry:</b> NOT HISPANIC OR LATIN	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)	O(A) OR OF SPANISH ORIGIN
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Dec-03-2020 16:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> WHITE	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-03-2020 16:10:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Dec-03-2020 16:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-03-2020 16:36:17 (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
Dec-03-2020 16:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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*1.a*

Date	Location	User	Value	Reason
Mar-18-2021 10:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Drug allergy Amoxicillin <b>Start Date:</b> UNK/UNK/2009 <b>Ongoing:</b> YES	Changed Information
Dec-03-2020 16:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Drug allergy Amoxicillin <b>Start Date:</b> UNK/UNK/1999 <b>Ongoing:</b> YES	Initial Entry
Dec-03-2020 16:39:24 (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> Drug allergy Amoxicillin <b>Start Date:</b> UNK/UNK/1999	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Dec-03-2020 16:39:24 (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
Dec-03-2020 16:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Drug allergy Amoxicillin	Initial Entry

**1.a Start Date:**

Date	Location	User	Value	Reason
Mar-18-2021 13:22:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-18-2021 10:44:15 (UTC-05:00) Eastern Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Changed Information

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

& Canada)				
Mar-18-2021 10:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> UNK/UNK/2009	Changed Information
Mar-18-2021 00:57:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Query 1: Opened	DM: Medical History Start Date is before the date of birth (b) (6) 2006). Please review and correct as appropriate.
Dec-03-2020 16:39:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> UNK/UNK/1999	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Dec-03-2020 16:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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
Dec-03-2020 16:36:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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-Oct-2020 16:04

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> 50.9	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Dec-03-2020	ACV0PF	Laura	<b>Data Entry:</b>	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

16:40:05 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	Pace (b) (4)	170.0	
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**5. Unit:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 17.6	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Record Identifier:</b> Temperature: 36.6 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> 36.6	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Dec-03-2020 16:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> 20753	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Dec-03-2020 16:40:44 (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
Dec-03-2020 16:40:44 (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
Dec-03-2020 17:50:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 16:40:44 (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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

				review and correct as appropriate.
Dec-03-2020 16:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Dec/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-03-2020 17:50:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP90K9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 17:50:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BP90K9	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-03-2020 17:51:09 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP90KB	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)

5.b Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 17:51:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BP90KB	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-03-2020 17:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BMRWDL</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 17:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BMRWDL	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Dec-03-2020 16:40:56 (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
Dec-03-2020 16:40:56 (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
Dec-03-2020 17:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 16:40:56 (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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

				review and correct as appropriate.
Dec-03-2020 16:40:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Dec/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-03-2020 17:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP90K6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-03-2020 17:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BP90K6	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**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
Dec-03-2020 16:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-03-2020 16:57:09 (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
Dec-03-2020 16:57:09 (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
Dec-03-2020 16:57:09	ACV0PF EINFP60	Laura Pace	<b>Data Entry:</b> Dec/3/2020 16:21	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-03-2020 16:57:09 (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
Dec-03-2020 16:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-03-2020 16:57:09 (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
Dec-03-2020 16:57:09	ACV0PF EINFP60	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

(UTC-05:00) Eastern Time (US & Canada)	00		D OBSERVATION PERIOD	
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***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

Date	Location	User	Value	Reason
Dec-03-2020 16:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Dec-03-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FO R THIS SUBJECT	Initial Entry



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-31-2020 02:08:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Closed as data entered.
Dec-30-2020 07:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 1: Answered	added
Dec-28-2020 04:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Vaccination Symptoms Diary - Symptom Resolved Date form' at this visit. Thank you.
Dec-22-2020 14:25:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/22/2020	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic N symptoms present on th O e last day the Subject D iary was completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FATIGU E <b>Were fever or sys</b> YES <b>temic symptoms</b> Ongoin <b>present on the las</b> g? <b>t day the Subject</b> <b>Diary was comple</b> NO <b>ted?:</b> Stop Date : De c/1 0/2 020	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Dec/10/2020	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b>  HE AD AC HE	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

			Were fever or systemic NO symptoms present on the last day the Subject Diary was completed? :	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic N symptoms present on the last day the Subject Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic NO symptoms present on the last day the Subject Diary was completed? :	
--	--	--	--	--

2.e Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<u>Data Entry:</u> 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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<u>Data Entry:</u> <u>Symptom::</u> DI AR RH EA	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic NO symptoms present on the last day the Subject Diary was completed?:	
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2.f Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed ?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<u>Data Entry:</u> NEW OR WORSENERD MUS CLE 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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<u>Data Entry:</u> <u>Symptom::</u> NEW O R WOR SENERD	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

			JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed? :	
--	--	--	---	--

**2.h Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD 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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52	ACV0PF EINFP60	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

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

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

Time (US & Canada)

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJ ECTIO N SIT E <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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
Dec-30-2020 07:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Dec-22-2020 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-22-2020 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Record Identifier 1</b> <b>r::</b> <b>Temperature: 36.4</b> <b>Temperature Unit: C</b> <b>Temperature Location: ORAL CAVITY</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-22-2020 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Dec-22-2020 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> 36.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Dec-22-2020 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-22-2020 15:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Dec-22-2020 15:02:30 (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
Dec-22-2020 15:02:30 (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
Dec-22-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 15:02:30 (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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

				review and correct as appropriate.
Dec-22-2020 15:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Dec/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-22-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP910N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-22-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BP910N	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Dec-22-2020 15:58:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-22-2020 15:58:48 (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
Dec-22-2020 15:58:48 (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
Dec-22-2020 15:58:48	ACV0PF EINFP60	Laura Pace	<b>Data Entry:</b> Dec/22/2020 15:18	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-22-2020 15:58:48 (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
Dec-22-2020 15:58:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-22-2020 15:58:48 (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
Dec-22-2020 15:58:48	ACV0PF EINFP60	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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

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

Date	Location	User	Value	Reason
Dec-22-2020 15:58:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **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-20-2021 15:50:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic symptoms present on th e last day the Subject D iary was completed?:</b> N O	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

*2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?*

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

2.b Symptom:

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or systemic NO</b> <b>symptoms present on t</b> <b>he last day the Subject</b> <b>Diary was completed?</b> :	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **Subject Initials:** ---

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

**2.c Symptom:**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic N</b> <b>symptoms present on th O</b> <b>e last day the Subject D</b> <b>iary was completed?:</b>	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

2.d Symptom:

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic NO</b> <b>symptoms present on t</b> <b>he last day the Subject</b> <b>Diary was completed?</b> :	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

2.e Symptom:

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

2.f Symptom:

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED MUSCL E PAIN  <b>Were fever or syst NO</b> <b>emic symptoms pr</b> <b>esent on the last d</b> <b>ay the Subject Dia</b> <b>ry was completed</b> <b>?:</b>	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

2.g Symptom:

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD MUS CLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERD JOINT P AIN  <b>Were fever or syst</b> NO <b>emic symptoms pr</b> <b>esent on the last d</b> <b>ay the Subject Dia</b> <b>ry was completed?</b> :	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

2.h Symptom:

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD JOIN T PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (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
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> RIGHT	Initial Entry

5.a

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction</b> RE : DN ES S  <b>Were injection site rea</b> NO <b>ctions present on the la</b> <b>st day the Subject Diar</b> <b>y was completed?:</b>	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> REDNESS	Initial Entry

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26	ACV0PF	Laura	<b>Data Entry:</b>	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)	EINFP6000	Pace (b) (4)	Injection Site Reaction: SWELLING  Were injection site reactions present on the last day the Subject Diary was completed?:	NO
--	-----------	-----------------	---	----

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	Laura Pace (b) (4)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	Laura Pace (b) (4)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **Subject Initials:** ---

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

			E	
<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>				
NO				

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **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-20-2021 15:50:38 (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-20-2021 15:50:38 (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-20-2021 17:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 15:50:38 (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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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: 1007 Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499 Subject Initials: ---

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

				appropriate.
Jan-20-2021 15:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 17:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRB8RY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 17:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRB8RY	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 17:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRB8RZ	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **Subject Initials:** ---

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

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-20-2021 17:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRB8RZ	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-20-2021 17:05:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWMPX	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-20-2021 17:05:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BNWMPX	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jun-28-2021 08:46:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	<b>Data Entry:</b> Jun/28/2021	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, Frozen, Verified

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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-28-2021 08:47:10 (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-28-2021 08:47:10 (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
Jun-28-2021 09:21:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-28-2021 08:47:10 (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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071499

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Jun-28-2021 08:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jun/28/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-28-2021 09:21:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTDN2D</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-28-2021 09:21:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTDN2D	Initial Entry

5.b

Date	Location	User	Value	Reason
Jun-28-2021 09:21:41 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTDN2F</b>	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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, Frozen, Verified

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

Eastern Time (US & Canada)

**5.b Sample ID**

Date	Location	User	Value	Reason
Jun-28-2021 09:21:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTDN2F	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jun-28-2021 09:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS0WKN	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jun-28-2021 09:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BS0WKN	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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-18-2021 09:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	<u>Data Entry:</u> Mar/18/2021	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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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
Mar-18-2021 09:35:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtai ned  Mar/18/2021	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **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-18-2021 09:35:52 (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-18-2021 09:35:52 (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-18-2021 11:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-18-2021 11:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071499**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Mar-18-2021 11:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-18-2021 09:35:52 (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.
Mar-18-2021 09:35:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Mar/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-18-2021 11:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BV03D7	Initial Entry
Mar-18-2021 11:31:39	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information

**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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **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)		
Mar-18-2021 11:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BV03D5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-18-2021 11:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BV03D7	Initial Entry
Mar-18-2021 11:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Mar-18-2021 11:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BV03D5	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Mar-18-2021 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BV03D8	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **Subject Initials:** ---

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

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-18-2021 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BV03D8	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-18-2021 11:34:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS2895	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-18-2021 11:34:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BS2895	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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-18-2021 09:36:07 (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-18-2021 09:36:07 (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
Mar-18-2021 11:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-18-2021 11:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection.

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071499 **Subject Initials:** ---**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				Please review and correct as appropriate.
Mar-18-2021 11:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-18-2021 09:36:07 (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.
Mar-18-2021 09:36:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Mar/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-18-2021 11:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BV03D5	Initial Entry

**5.a Sample ID**

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Mar-18-2021 11:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BV03D5	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Mar-18-2021 11:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BV03D8</b>	Changed Information <b>(DELETED)</b>
Mar-18-2021 11:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BV03D8</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-18-2021 11:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BV03D8	Changed Information <b>(DELETED)</b>
Mar-18-2021 11:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BV03D8	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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-20-2021 15:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-20-2021 15:51:47 (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
Jan-20-2021 15:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/01/2021

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Apr-01-2021 09:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/1/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-01-2021 09:19:54 (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 Apr/01/2021

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-01-2021 09:20:07 (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-01-2021 09:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-01-2021 09:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-01-2021 09:20:07 (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

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/01/2021

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

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

				review and correct as appropriate.
Apr-01-2021 09:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/1/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-01-2021 09:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> AA02045	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-01-2021 09:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> AA02045	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/15/2021

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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-16-2021 11:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/15/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-16-2021 11:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK4	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/15/2021

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-16-2021 11:46:07 (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-16-2021 11:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-16-2021 11:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-16-2021 11:46:07 (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

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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/15/2021

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

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

				review and correct as appropriate.
Apr-16-2021 11:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/15/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-16-2021 11:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> AA03045	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-16-2021 11:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> AA03045	Initial Entry

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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/29/2021

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Apr-30-2021 11:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/29/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-30-2021 11:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK6	Initial Entry

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/29/2021

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-30-2021 11:24:39 (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
Apr-30-2021 11:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-30-2021 11:24:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-30-2021 11:24:39 (UTC-05:00)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/29/2021

**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Apr-30-2021 11:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/29/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-30-2021 11:24:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> AA03047	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-30-2021 11:24:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> AA03047	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**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 07:10:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> May/4/2021	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**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, Verified

**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499 **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-19-2021 07:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national r ecommendations and confi rmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
May-24-2021 13:39:27 (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
May-24-2021 13:39:27 (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
May-26-2021 10:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
May-26-2021 10:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Changed Information

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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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

Canada)				
May-26-2021 10:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> left wrist pain	Changed Information
May-25-2021 12:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please clarify if wrist pain is Left, Right or Bilateral. Thank you!
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> wrist pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> May/1/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
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090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO End Date Time:  May/3/2021 UNK:UNK	Initial Entry
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**6. Toxicity Grade:**

Date	Location	User	Value	Reason
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<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.***

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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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jun-11-2021 13:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
May-28-2021 09:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:C andidate	Please confirm if Trauma need to be added as AE or if query can be closed.
May-27-2021 12:20:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 1: Answered	please clarify; subject was playing soccer
May-27-2021 05:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:O pened	DM: Kindly confirm if trauma was due to subject or external factor. Thank you.

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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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

May-26-2021 10:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
May-26-2021 10:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 1: Answered	due to soccer injury
May-26-2021 10:35:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 2: Answered	soccer injury
May-25-2021 12:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	clinical: please advise on nature of trauma eg fall vs other accident etc. Thanks
May-25-2021 11:57:50 (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 [Trauma]. Any symptoms, AEs or other

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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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071499**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44

				key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Trauma	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
May-24-2021 13:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
May-19-2021 07:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Jun-30-2021 10:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
May-19-2021 07:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
May-19-2021 07:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
May-19-2021 07:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
May-25-2021 12:40:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
May-24-2021 13:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
May-24-2021 13:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> SARS-CoV-2 vaccination Pfizer	New Information
May-21-2021 18:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Please confirm the proprietary name or manufacturer of the covid vaccine that was administered to participant. Review and update as appropriate.
May-19-2021 07:09:34	ACV0PF EINFP60	Laura Pace (b) (4)	<b>Data Entry:</b> SARS-CoV-2 vaccination	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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

00

**5. Date:**

Date	Location	User	Value	Reason
May-19-2021 07:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> May/13/2021	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jun-30-2021 10:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jun-30-2021 10:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jun-30-2021 10:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
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090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

Jun-30-2021 10:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> SARS-CoV-2 mRNA vaccine Pfizer	Initial Entry
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**5. Date:**

Date	Location	User	Value	Reason
Jun-30-2021 10:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Jun/4/2021	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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-19-2021 07:09:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> May/12/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
May-19-2021 07:09:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071499

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

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

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject Initials:** ---

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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jun-29-2021 13:21:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Jun-29-2021 13:21:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**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
Jun-24-2021 04:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Jun-23-2021 08:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4) [REDACTED]	Query 1: Answered	Participant and family opted to have participant vaccinated with outside study; participant no longer qualifies for Asymptomatic swab collection
Jun-22-2021 23:48:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	PDQ: WEEK6 surveillance swab was done on 29APR2021 and repeat swab is expected to perform every 10 to 18 Days after each surveillance swab Collection. However, repeat

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**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:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

				swab Week 8,10,12 is missing. Please clarify the reason for missing swab and confirm PD.
Jan-20-2021 15:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-03-2020 16:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Dec-03-2020 16:36:17 (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
Jan-20-2021 15:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Jan/20/2021	Initial Entry
Dec-03-2020 16:40:27	ACV0PF EINFP60	auto calc (autocalc)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical Center

**Subject No:** 10071499

**Subject Initials:** ---

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

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

(UTC-05:00) Eastern Time (US & Canada)	00			
Dec-03-2020 16:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1007

**Subject No:** 10071499

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center

**Subject Initials:** ---

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

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Mar-15-2021 20:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e19891a039\Final\Final On: 11-Nov-2021 01:20 (GMT)