

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[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

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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/2/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10071497]
2.	Birth Date:	(b) (6) 2008
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 15-Sep-2020 21:52**Site No:** 1007**Subject No:** 10071497**Generated By:** (b) (4)**Form:** DISPOSITION - SCREENING**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Dec/2/2020
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:** 10071497

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Attention deficit/hyperactivity disorder]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** HIV STATUS

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[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:** 10071497**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Dec/2/2020
2.	Weight:	[39.0]
3.	Unit:	kg
4.	Height:	[151.0]
5.	Unit:	cm
6.	Body Mass Index:	[17.1]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[37.2]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Dec/2/2020
2.	Randomization Number:	[20746]
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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/2/2020
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	[BP90J8]
5.b	Sample ID	[BMRWC9]
5.c	Sample ID	[BP90J9]

**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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/2/2020
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	[BP90J7]
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**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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/2/2020 17:22
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Site No:** 1007

**Subject No:** 10071497

**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):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/22/2020
2.	Erroneous Visit	

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[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

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**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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

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

**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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VITAL SIGNS - TEMP**Form Version:** 10-Dec-2020 02:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Vital Signs**

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

2.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[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	[BP9106]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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 09:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

**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:** 10071497 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:12

[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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[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

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**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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

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**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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

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**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_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:** 10071497 **Subject Initials:** ---**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:12[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	[BRB8RB]
5.b	Sample ID	[BRB8RC]
5.c	Sample ID	[BNWMPG]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1007

**Subject No:** 10071497

**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):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

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**Header Text:** c4591001**Visit:** V4\_MONTH6\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1007

**Subject No:** 10071497

**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):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** V5\_MONTH12\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** 10071497

**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):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** V6\_MONTH24\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form Version:** 20-Feb-2021 02:17**Site No:** 1007**Subject No:** 10071497**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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 Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071497**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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 Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071497**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form:** HEALTH CARE UTILIZATION**Form Version:** 20-Feb-2021 02:19**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**Health Care Utilization**

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

**Health Care Utilization Other**

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

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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**Header Text:** c4591001

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

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** ILLNESS DETAILS

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**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:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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\_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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**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:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	swollen lymph node left axilla	Dec/25/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071497**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[swollen lymph node left axilla]
4.	Start Date Time:	Dec/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**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	[ ]

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS -  
PROHIBITED

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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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?	

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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



**Header Text:** c4591001

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

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

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

**Subject No:** 10071497      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 10071497    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** Unplanned Vaccination -  
Unscheduled**Form:** VITAL SIGNS - TEMP**Form Version:** 20-Feb-2021 02:16**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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?	

**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** CONTACT OUTCOME - MONTH 6

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** Not Started

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Informed Consent - Asymptomatic Surveillance**

1. Consent Was:

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**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:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[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:	[ ]

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

Unscheduled

**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
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:** Not Started

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Further Vaccination Confirmation**

- |    |   |  |
|----|---|--|
| 1. | Select appropriate response<br>- Is participant willing to<br>return for Vaccination 3? |  |
|----|---|--|

**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:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Treatment Unblinded**

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



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Death Details**

1.	Date of Collection / Notification of Death:	//
----	---	----

**Cause of Death**

2.	Cause of Death Status:	
	Cause of Death:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Jan/20/2021

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Casebook Signature Form**

1.	Casebook Signature	
----	--------------------	--

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-02-2020 17:10:36 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form:** COHORT SELECTION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:01**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Dec-02-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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-02-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Dec-02-2020 17:09:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Dec/2/2020	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Dec-02-2020 17:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10071497	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-02-2020 17:09:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2008	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Dec-02-2020 17:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-02-2020 17:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT HISPANIC OR L ATINO(A) OR OF SP ANISH ORIGIN	Initial Entry
---	-----------------	--------------------------	--	---------------

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

Date	Location	User	Value	Reason
Dec-02-2020 17:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> ASIAN	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

**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):** 29-Mar-2021 04:12

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***1. Date of Visit***

Date	Location	User	Value	Reason
Dec-02-2020 17:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> Dec/2/2020	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Dec-02-2020 17:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-02-2020 17:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-02-2020 17:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Dec-02-2020 18:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 1 <b>H Num</b> <b>ber:</b> <b>Medical</b> Attention de <b>History</b> ficit/hyperac <b>Term:</b> tivity disord er <b>Start D</b> UNK/UNK/ <b>ate:</b> 2017 <b>Ongoin</b> YES <b>g:</b>	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Dec-02-2020 18:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
------	----------	------	-------	--------

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-02-2020  
18:06:41  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura  
Pace  
(b) (4)

**Data Entry:**  
Attention deficit/hyper  
activity disorder

Initial Entry

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

**Date**

**Location**

**User**

**Value**

**Reason**

Dec-02-2020  
18:06:41  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura  
Pace  
(b) (4)

**Data Entry:**  
UNK/UNK/2017

Initial Entry

***1.a Ongoing:***

**Date**

**Location**

**User**

**Value**

**Reason**

Dec-02-2020  
18:06:41  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura  
Pace  
(b) (4)

**Data Entry:**  
YES

Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Dec-02-2020 18:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 Version:** 10-Oct-2020 16:04**Site No:** 1007**Subject No:** 10071497**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 39.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 151.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 17.1	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Record Ide</b> 1	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Eastern Time (US  
& Canada)

**ntifier::**

**Temperatur** 37.2

**e:**

**Temperatur C**

**e Unit:**

**Temperatur** ORAL

**e Location::** CAVIT  
Y

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Dec-02-2020 18:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 37.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-02-2020  
18:04:26  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura  
Pace  
(b) (4)

**Data Entry:**  
C

Initial Entry

***7.a Temperature Location:***

**Date**

**Location**

**User**

**Value**

**Reason**

Dec-02-2020  
18:04:26  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura  
Pace  
(b) (4)

**Data Entry:**  
ORAL CAVITY

Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Dec-02-2020 18:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Dec-02-2020 18:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 20746	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

### 1. Data Origin

Date	Location	User	Value	Reason
Dec-02-2020 17:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

### 2. Sample Type

Date	Location	User	Value	Reason
Dec-02-2020 17:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

### 3. Sample Collected?

Date	Location	User	Value	Reason
Dec-02-2020 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-02-2020 17:11:49	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

**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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-02-2020 17:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collecti on:  Dec/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-02-2020 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BP90J <b>D:</b> 8	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-02-2020 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP90J8	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.b**

Date	Location	User	Value	Reason
Dec-02-2020 17:12:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BMRW</b> <b>D: C9</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-02-2020 17:12:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>BMRWC9</b>	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-02-2020 17:12:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BP90J</b> <b>D: 9</b>	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-02-2020 17:12:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP90J9	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL 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):** 29-Mar-2021 04:12

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### 1. Data Origin

Date	Location	User	Value	Reason
Dec-02-2020 17:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

### 2. Sample Type

Date	Location	User	Value	Reason
Dec-02-2020 17:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

### 3. Sample Collected?

Date	Location	User	Value	Reason
Dec-02-2020 17:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-02-2020 17:11:24	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

**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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-02-2020 17:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collecti on:  Dec/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-02-2020 17:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BP90J <b>D:</b> 7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-02-2020 17:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP90J7	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

Date	Location	User	Value	Reason
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1007**Subject No:** 10071497**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-02-2020 18:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-02-2020 18:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/2/2020 17:22	Transcription Error
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date, 02/Dec/2020 19:22 is a future date relative to when it was entered on 02/Dec/2020 18:06. Please correct.
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/2/2020 19:22	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-02-2020 18:06:09 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**Header Text:** c4591001

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

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**Site No:** 1007

**Subject No:** 10071497

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

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

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

**Subject Initials:** ---

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Eastern Time (US  
& Canada)

**6. Body Side:**

Date	Location	User	Value	Reason
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

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**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

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Date	Location	User	Value	Reason
Dec-02-2020 18:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> YES	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Dec-02-2020 18:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES - REACTOGENI CITY E-DIARY COL LECTED FOR THIS S UBJECT	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071497

**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):** 29-Mar-2021 04:12

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***1. Date of Visit***

Date	Location	User	Value	Reason
Dec-22-2020 10:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> Dec/22/2020	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  <b>Were fever or sys N</b> <b>temic symptoms O</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1007

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**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or sys N</b> <b>temic symptoms O</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

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**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.b Symptom:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1007

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**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

			Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44	ACV0PFEINFP6000	Laura Pace	<b>Data Entry:</b> <b>Symptom::</b> C	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
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History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	HI L LS  Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	
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**2.d Symptom:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG  <b>Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:</b>	Initial Entry
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**2.e Symptom:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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**Subject Initials:** ---

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

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2.f

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or sy NO</b> <b>stemic symptom</b> <b>s present on the l</b> <b>ast day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry



**Header Text:** c4591001

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**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.f Symptom:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUSC LE PA IN	Initial Entry

**Header Text:** c4591001

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**Subject No:** 10071497

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			Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
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**2.g Symptom:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR WORSENE D MUSCLE 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-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
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**Subject No:** 10071497

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

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Dec-22-2020  
10:19:44  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura  
Pace  
(b) (4)

**Data Entry:**

**Symptom::** NEW  
OR W  
ORSE  
NED J  
OINT  
PAIN

**Were fever or NO  
systemic sym  
ptoms presen  
t on the last d  
ay the Subjec  
t Diary was c  
ompleted?:**

Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

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**Visit:** V2\_VAX2\_L

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.h Symptom:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
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090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Subject Initials:** ---

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

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Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> REDNESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW EL LI NG <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site</b> PAIN <b>Reaction::</b> AT I NJE CTIO N SI TE	Initial Entry

**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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

			Were injection NO site reactions p resent on the l ast day the Su bject Diary wa s completed?:	
--	--	--	---	--

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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-22-2020 10:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Dec-22-2020 10:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-22-2020 10:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.1 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-22-2020 10:18:28 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Eastern Time (US  
& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Dec-22-2020 10:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 37.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Dec-22-2020 10:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-22-2020 10:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 10:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-22-2020 10:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-22-2020 12:07:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 10:18:38	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 10:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:07:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9106	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-22-2020 12:07:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9106	Initial Entry

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1007**Subject No:** 10071497**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/22/2020 09:50	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071497

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 11:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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***1. Date of Visit***

Date	Location	User	Value	Reason
Jan-20-2021 12:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> Jan/20/2021	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**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 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R <b>Were fever or sys N</b> <b>temic symptoms O</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or sys N</b> <b>temic symptoms O</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE	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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

			Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13	ACV0PFEINFP6000	Laura Pace	<b>Data Entry:</b> Symptom:: C	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4)

HI  
L  
LSWere fever or sys N  
temic symptoms O  
present on the las  
t day the Subject  
Diary was compl  
eted?:**2.d Symptom:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
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**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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG  <b>Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:</b>	Initial Entry
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**2.e Symptom:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

2.f

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or sy NO</b> <b>stemic symptom</b> <b>s present on the l</b> <b>ast day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUSC LE PA IN	Initial Entry



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

			Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
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**2.g Symptom:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR WORSENE D MUSCLE 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 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
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090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED J OINT PAIN  <b>Were fever or NO systemic sym ptoms presen t on the last d ay the Subjec t Diary was c ompleted?:</b>	Initial Entry
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**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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.h Symptom:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
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090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> REDNESS  Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
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**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW EL LI NG <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site</b> PAIN <b>Reaction::</b> AT I NJE CTIO N SI TE	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, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

			Were injection NO site reactions p resent on the l ast day the Su bject Diary wa s completed?:	
--	--	--	---	--

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-20-2021 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-20-2021 12:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-20-2021 12:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-20-2021 12:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 12:07:59	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is



**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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 12:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRB8R : B	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-20-2021 12:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRB8RB	Initial Entry

**5.b**

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Jan-20-2021 12:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRB8R : C	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-20-2021 12:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRB8RC	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-20-2021 12:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNWMP <b>D:</b> G	Initial Entry

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING -  
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**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:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-20-2021 12:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWMPG	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

**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):** 29-Mar-2021 04:12

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Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Category:**

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Jan-05-2021 15:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 19:49:42	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

**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**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071497**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				
Jan-04-2021 19:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> swollen lymph node left axilla	Changed Information
Jan-04-2021 18:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please update term to indicate exact location of swollen lymph node, for example, "swollen Right anterior cervical lymph node" or "swollen left axillary lymph node", etc.
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> swollen lymph node	Initial Entry

**4. Start Date Time:**

**Header Text:** c4591001

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**Site No:** 1007

**Subject No:** 10071497

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/25/2020 UNK:UN K	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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**

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**Site No:** 1007

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

**Subject No:** 10071497

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

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*medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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.*

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
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**Form Status:** Data Complete

**Site No:** 1007

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

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERING/RESO LVING	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

& Canada)

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

Date	Location	User	Value	Reason
Jan-04-2021 08:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071497

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Jan-20-2021 12:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 12:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-20-2021 12:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071497

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

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

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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**1. Subject Status**

Date	Location	User	Value	Reason
Jan-20-2021 12:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-02-2020 18:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Dec-02-2020 17:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Jan-20-2021 12:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/20/2021	Initial Entry
Dec-02-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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**Site No:** 1007

**Subject No:** 10071497

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

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

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

18:05:33 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Dec/2/2020	
Dec-02-2020 17:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b><u>Data Entry:</u></b> Dec/2/2020	Initial Entry

090177e196ae30a7\Final\Final On: 01-Apr-2021 04:11 (GMT)