

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

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

**Site No:** 1007

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

**Subject No:** 10071620

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071620

**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/30/2020

**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form:** DEMOGRAPHY**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Demography**

1.	Subject ID	[10071620]
2.	Birth Date:	(b) (6) 2008
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 15-Sep-2020 21:52**Site No:** 1007**Subject No:** 10071620**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/30/2020
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:** 10071620**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 disorder]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-Dec-2020 02:29**Site No:** 1007**Subject No:** 10071620**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/30/2020
2.	Weight:	[57.1]
3.	Unit:	kg
4.	Height:	[155.5]
5.	Unit:	cm
6.	Body Mass Index:	[23.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[37.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**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](#)**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Dec/30/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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/30/2020
2.	Randomization Number:	[24828]
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:** 10071620**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/30/2020
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	[BR3Y9X]
5.b	Sample ID	[BR3Y9Y]
5.c	Sample ID	[BMNR57]

**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:** 10071620**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/30/2020
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	[BR3Y9H]
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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1007**Subject No:** 10071620**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/30/2020 10:26
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

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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	Jan/20/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 14-Jan-2021 02:22**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP**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:	Jan/20/2021
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**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**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](#)**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/20/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

**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:** 10071620**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: 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	[BRB8S5]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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:	Jan/20/2021 16:30
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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**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:** 10071620 **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	Feb/18/2021
2.	Erroneous Visit	



**Header Text:** c4591001

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

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

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

**Subject No:** 10071620 **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?	YES Ongoing? YES
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? YES
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? YES

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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?	YES Ongoing? NO Stop Date: Jan/27/2021
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?	YES Ongoing? NO Stop Date: UNK/UNK/2021
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? YES

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**Header Text:** c4591001

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? YES
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

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**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: Feb/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR0ZV6]
5.b	Sample ID	[BR0ZV7]
5.c	Sample ID	[BNWN2L]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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:** 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:** 10071620**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:** 10071620

**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:** 10071620**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:** 10071620

**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 Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject Initials:** ---**Generated Time (GMT):** 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	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

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

**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	Feb/5/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
----	-------------------------	---------

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

**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](#)

**Signs and Symptoms**

1.	Date of Assessment:	Feb/5/2021
2.	Date of First Symptom Started:	Feb/5/2021
3.	Symptoms Ongoing?	YES

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

**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

4.g

Symptoms:

NEW OR INCREASED SORE THROAT

Was symptom present?

NO

4.h

Symptoms:

DIARRHEA

Was symptom present?

YES

4.i

Symptoms:

VOMITING

Was symptom present?

NO

**Symptoms - Other**

5.

Symptoms - Other Text:

[ ]

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN

**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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[Form Comments](#)

[eCRF Audit Trail History](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Not Done _____ //	<a href="#">Comments</a>
2.	Specimen Type:	Not Done _____	<a href="#">Comments</a>
3.	Specimen Collection Location:	Not Done _____	<a href="#">Comments</a>
4.	Assay Code and Description:	Not Done _____	<a href="#">Comments</a>
5.	Device Type:	Not Done _____	<a href="#">Comments</a>
6.	Trade Name:	Not Done _____	<a href="#">Comments</a>
7.	Test Result:	Not Done _____	<a href="#">Comments</a>
8.	Comments/Findings /Details:	Not Done _____ [ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	Not Done _____ [ ]	<a href="#">Comments</a>

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**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](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**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](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 14-Jan-2021 02:24

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ILLNESS DETAILS

**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](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ILLNESS DETAILS - SEVERE

**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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**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Dec-2020 02:24

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/05/2021

**Form Version:** 10-Dec-2020 02:24

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**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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**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Dec-2020 02:28

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

#	Category f or Lab Tes t	Vendor Nam e (DERIVED )	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 10-Dec-2020 02:28

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**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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**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/05/2021

**Form:** VITAL SIGNS - COVID

**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:** 10071620

**Subject Initials:** ---

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

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

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### Vital Signs

1. Date: //

### Vital Signs Details

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/05/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**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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### Vital Signs

1. Date: //

### Vital Signs Details

2. Record Identifier:   
 SPO2 Pulse Oximetry % [ ]



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** OXYGENATION PARAMETERS

**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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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1007

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

**Subject No:** 10071620

**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:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**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.	Start Date:	//
6.	Ongoing?	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**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:** 10071620

**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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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (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:** 10071620**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:** 10071620

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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (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:** 10071620**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:** 10071620

**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	Vulvar boil	Jan/24/2021 UNK:UNK	NO End Date Time :  Jan/26/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Abdominal pain	Jan/21/2021 UNK:UNK	NO End Date Time :  Feb/9/2021 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	generalized Functional neurologic pain	Jan/21/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Gastritis	Jan/30/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>
5. DELETED	ADVERSE EVENT	5	diarrhea	Feb/5/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	contact dermatitis bilateral arms	Feb/12/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT

**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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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Vulvar boil]
4.	Start Date Time:	Jan/24/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/26/2021 UNK:UNK
6.	Toxicity Grade:	1

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT

**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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT

**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

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**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](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Abdominal pain]
4.	Start Date Time:	Jan/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/9/2021 UNK:UNK
6.	Toxicity Grade:	2

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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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?	YES

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**Header Text:** c4591001

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**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Verified**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:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[generalized Functional neurologic pain]
4.	Start Date Time:	Jan/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p>If Other, specify:</p> <p>[unspecified]</p>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[2021101980]

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**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:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Gastritis]
4.	Start Date Time:	Jan/30/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**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:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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**Subject No:** 10071620

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**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	[ ]

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Deleted**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	<del>ADVERSE EVENT</del>
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[diarrhea]
4.	Start Date Time:	<del>Feb/5/2021 UNK:UNK</del>
5.	Is the adverse event still ongoing?	<del>YES</del>
6.	Toxicity Grade:	4



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Deleted

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Deleted**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**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:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[contact dermatitis bilateral arms]
4.	Start Date Time:	Feb/12/2021 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:** 10071620**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.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p>If Other, specify:</p> <p>[suspected reaction to tape]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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

11.	Was a Concomitant Medication given?	YES
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	[ ]

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**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:** 10071620

**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:** 10071620

**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

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**Medication Error**

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

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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:** 10071620

**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:	//

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**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:** 10071620

**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:** 10071620

**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?	

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**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:** 10071620

**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:** 10071620

**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?	

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**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:** 10071620

**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:** 10071620

**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 1 - Unscheduled  
Visit on Jan/21/2021

**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:** 10071620

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Jan/21/2021

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

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**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
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**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled  
Visit on Jan/21/2021**Form:** CONTACT OUTCOME - UNPLANNED**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES  Date of Contact: Jan/21/2021  Contact Outcome: VISIT NOT ARRANGED, UNABLE TO ATTEND
3.	Comments:	[ ]

**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:** 10071620

**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:** 10071620**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:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

**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:** 10071620**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:** 10071620

**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:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071620

**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:** 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:** 10071620

**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:** 10071620

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

1. Consent Was:

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**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	[ ]
----	-----------	-----

**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:** 10071620**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	[ ]
----	-----------	-----

**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:** 10071620

**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 :	Feb/18/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (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:** 10071620

**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:** 10071620

**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:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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:** 10071620

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

**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:** Follow-Up - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

**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:** 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:** 10071620

**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	Feb/18/2021

**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:** 10071620

**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:** 10071620

**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:** 10071620

**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-30-2020 09:41:26 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Applicable

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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
1	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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
2	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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
3	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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

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Item	Date	User	Comment
4	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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
5	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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
6	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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
7	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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
8	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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

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Item	Date	User	Comment
9	Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Done

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form:** COHORT SELECTION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:31**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**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
Jan-30-2021 16:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 01 DEC 2020	Changed Information
Dec-30-2020 09:40:39 (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-30-2020 09:40:39 (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:** 10071620**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-30-2020 09:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Dec/30/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071620

**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

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**1. Subject ID**

Date	Location	User	Value	Reason
Dec-30-2020 09:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10071620	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-30-2020 09:40:25 (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-30-2020 09:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 09:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> HISPANIC OR LATIN O(A) OR OF SPANIS H ORIGIN	Initial Entry
---	-----------------	--------------------------	--	---------------

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

Date	Location	User	Value	Reason
Dec-30-2020 09:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 09:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 11:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-30-2020 11:08:57 (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-30-2020 11:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**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[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Dec-30-2020 11:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical History Term:</b> Attention deficit disorder <b>Start Date</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 11:15:46 (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
Dec-30-2020 11:15:46 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Attention deficit disorder	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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

Eastern Time (US  
& Canada)

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

Date	Location	User	Value	Reason
Dec-30-2020 11:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Dec-30-2020 11:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 11:09:08 (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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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

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**1. Date:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 57.1	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 11:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 155.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:24 (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-30-2020 11:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23.6	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:24 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Record Id</b> 1	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12Eastern Time (US  
& Canada)**Identifier::****Temperature:** 37.3**Unit:****Temperature Unit:****Temperature Location:** ORAL**Temperature Location:** CAVITY**7.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:24 (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-30-2020 11:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 37.3	Initial Entry

**7.a Unit:**

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

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Dec-30-2020  
11:13:24  
(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-30-2020  
11:13:24  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura  
Pace  
(b) (4)

**Data Entry:**  
ORAL CAVITY

Initial Entry

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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST -  
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. Lab Panel:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**



**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
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-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
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

**Not Done**

::

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Choriogonadotropin B eta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Dec-30-2020 11:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 11:14:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Dec-30-2020 11:14:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 24828	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-30-2020 11:14:50 (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-30-2020 11:14:50 (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-30-2020 14:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 11:14:50	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**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(UTC-05:00)  
Eastern Time (US  
& Canada)Yes, however  
no barcodes  
are entered.  
Please review  
and correct as  
appropriate.Dec-30-2020  
11:14:50  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura Pace  
(b) (4)**Data Entry:**  
YES  
Date of Collection:  
  
Dec/30/2020

Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-30-2020 14:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BR3Y9 : X	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-30-2020 14:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR3Y9X	Initial Entry

**5.b**

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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

Date	Location	User	Value	Reason
Dec-30-2020 14:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BR3Y9 : Y	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-30-2020 14:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR3Y9Y	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-30-2020 14:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BMNR5 : 7	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 14:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMNR57	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 11:15:01 (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-30-2020 11:15:01 (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-30-2020 15:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 11:15:01	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:** 10071620**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-30-2020 11:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Dec/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-30-2020 15:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BR3Y9 : H	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-30-2020 15:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR3Y9H	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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

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

Date	Location	User	Value	Reason
Dec-30-2020 11:16:58 (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-30-2020 11:16:58 (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-30-2020 11:16:58 (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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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 11:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Dec/30/2020 10:26	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-30-2020 11:16:58 (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-30-2020 11:16:58 (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-30-2020 11:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 11:16:58 (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-30-2020 11:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071620

**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-30-2020 11:15:12 (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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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
Jan-20-2021 16:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**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 16:16:39 (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 16:16:39 (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  
History

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Jan-20-2021 16:16:39 (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 16:16:39 (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 16:16:39 (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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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 16:16:39 (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 16:16:39 (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 16:16:39 (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

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
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**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1007

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

**Subject No:** 10071620

**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 16:16:39 (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 16:16:39 (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 16:16:39	ACV0PFEINFP6000	Laura Pace	<b>Data Entry:</b> <b>Symptom::</b> C	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**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
Jan-20-2021 16:16:39 (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 16:16:39 (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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Jan-20-2021 16:16:39 (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 16:16:39 (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 16:16:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
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**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

2.f

Date	Location	User	Value	Reason
Jan-20-2021 16:16:39 (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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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History

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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 16:16:39 (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 16:16:39 (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 16:16:39 (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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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History

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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 16:16:39 (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 16:16:39 (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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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Jan-20-2021  
16:16:39  
(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



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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 16:16:39 (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 16:16:39 (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 16:16:39 (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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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Jan-20-2021 16:16:39 (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 16:16:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE D NE SS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-20-2021 16:16:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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 16:16:39 (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 16:16:39 (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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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 16:16:39 (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 16:16:39 (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 16:16:39 (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-Dec-2020 02:30

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

**Site No:** 1007

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

**Subject No:** 10071620

**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?:	
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-20-2021 16:16:39 (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 16:16:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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

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**1. Date:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.2 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:31 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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
Jan-20-2021 16:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 37.2	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:31 (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
Jan-20-2021 16:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST -  
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. Lab Panel:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject No:** 10071620

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

			<b>Not Done</b> ::	
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Choriogonadotropin B eta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-20-2021 16:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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
Jan-20-2021 16:15:50 (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 16:15:50 (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
Jan-20-2021 16:25:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 16:15:50	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:** 10071620**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 16:15:50 (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 16:25:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BRB8S D: 5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-20-2021 16:25:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRB8S5	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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

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

Date	Location	User	Value	Reason
Jan-20-2021 17:09:01 (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
Jan-20-2021 17:09:01 (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
Jan-20-2021 17:09:01 (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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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

**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

Jan-20-2021 17:09:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/20/2021 16:30	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-20-2021 17:09:01 (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
Jan-20-2021 17:09:01 (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
Jan-20-2021 17:09:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071620

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-20-2021 17:09:01 (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
Jan-20-2021 17:09:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (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:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)***1. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Mar-03-2021 02:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-02-2021 17:20:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 2: Answered	updated
Feb-25-2021 21:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Kindly review and complete 'Vaccination Symptoms Diary - Symptom Resolved Date form' at this visit. Thank you.
Feb-18-2021 18:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Feb/18/2021	Initial Entry
Jan-28-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site



**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:** 10071620

**Subject Initials:** ---

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

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

02:59:33 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		confirmation_PD tracker updated
Jan-27-2021 08:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 1: Answer ed	completed
Jan-26-2021 09:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Patient reported experiencing severe symptoms in ediary. Please complete an unplanned visit.

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Ongoing?  YES	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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 -  
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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:** 10071620

**Subject Initials:** ---

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

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

Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FATI GUE  <b>Were fever or s YES</b> <b>ystemic sympt Ong</b> <b>oms present on oin</b> <b>the last day the g?</b> <b>Subject Diary</b> <b>was completed Y</b> <b>?: E</b> S	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY -  
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**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject No:** 10071620

**Subject Initials:** ---

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

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

**2.b Symptom:**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Ongoing?  YES	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> HEA DAC HE	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (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:** 10071620

**Subject Initials:** ---

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

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

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	YES Ongoing? Y ES	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Ongoing?  YES	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Mar-03-2021	ACV0PFEINFP6000	Laura	<b>Data Entry:</b>	Changed

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

12:54:04 (UTC-05:00) Eastern Time (US & Canada)		Pace (b) (4)	<b>Symptom::</b> CHILL S  <b>Were fever</b> YES <b>or systemic</b> Ongoing? <b>symptoms p</b> ng? <b>resent on th</b> <b>e last day th</b> NO <b>e Subject Di</b> <b>ary was co</b> Sto <b>mpleted?:</b> p D ate:  Ja n/ 2 7/ 2 0 2 1	Information
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> CHILL S	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject No:** 10071620

**Subject Initials:** ---

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

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

			<p><b>Were fever or systemic symptoms present on the last day of the Subject Diary was completed?:</b></p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Jan/21/2021</p>	
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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:** 10071620

**Subject Initials:** ---

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

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

**2.d Symptom:**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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
Mar-04-2021 00:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Mar-03-2021 12:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-03-2021 12:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:	Changed Information

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)



**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

			Jan/27/2021	
Mar-03-2021 07:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, Day 7 is the last day reported on 26-Jan-2021. However, in Inform for CHILLS stop date is provided as 21-Jan-2021. Please verify and consider to update as needed. Else, clarify. Thanks
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> YES Ongoing?  NO  Stop Date:  Jan/21/2021	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  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

2.f

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> DIARRH EA <b>Were fever YES</b> <b>or systemic Ongoing?</b> <b>symptoms p g?</b> <b>resent on th</b> <b>e last day th</b> NO <b>e Subject Di</b> <b>ary was co</b> Stop <b>mpleted?:</b> Date :  U N K/ U N K/ 20 21	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

**2.f Symptom:**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  UNK/UNK/2021	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED MUSCL	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

			E PAIN	
			Were fever YES	
			or systemic Ongoing?	
			symptoms present on the last day the Subject Diary was completed?:	
			YES	

**2.g Symptom:**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Ongoing?  YES	Initial Entry

**2.h**

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-Dec-2020 02:30

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED JOINT P AIN  <b>Were fever</b> YES <b>or systemic</b> Ongoing? <b>symptoms p</b> <b>resent on th</b> <b>e last day th</b> YES <b>e Subject Di</b> <b>ary was com</b> <b>pleted?:</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-Dec-2020 02:30

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

**2.h Symptom:**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Ongoing?  YES	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**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
Mar-02-2021 17:20:18 (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
Mar-02-2021 17:20:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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
Feb-18-2021 18:38:53 (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
Feb-18-2021 18:38:53 (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
Feb-19-2021 08:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-19-2021 06:27:20	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'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:** 10071620**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.
Feb-18-2021 18:38:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-18-2021 18:38:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Feb/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-19-2021 08:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR0ZV <b>D:</b> 6	Initial Entry

**5.a Sample ID**

**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:** 10071620

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Feb-19-2021 08:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR0ZV6	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-19-2021 08:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR0ZV <b>D:</b> 7	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 08:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR0ZV7	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-19-2021 08:58:52 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNWN	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Eastern Time (US  
& Canada)

**D:** 2L

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 08:58:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWN2L	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - 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 of Visit*

Date	Location	User	Value	Reason
Feb-18-2021 16:31:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 07:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 1: Answered	correct subject did not do swab; protocol deviation submitted
Feb-17-2021 05:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-16-2021 08:58:25	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/05/2021

**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - 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

(UTC-05:00) Eastern Time (US & Canada)				
Feb-16-2021 08:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-16-2021 08:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-16-2021 08:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

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

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - 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
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> FEVE R <b>Symptom Pre NO sent:</b>	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25	ACV0PFEINFP6000	Laura Pace	<b>Data Entry:</b> <b>Sympto NEW OR IN</b>	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

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

(b) (4)

**ms:** CREASED  
COUGH

**Symptom Present:** NO

**4.b Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR INCREASE D COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INC CREASED SHORTNESS OF	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

& Canada)			BREATH Sym NO tom P resent :	
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL LS	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

& Canada)

**Symptom Pre NO  
sent:**

**4.d Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Sympt NEW OR IN</b> <b>oms: CREASED M</b> <b>USCLE PAIN</b>  <b>Sympt NO</b> <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

**4.e Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR INCREASE D MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Sympt</b> NEW LOSS <b>oms:</b> OF TASTE O R SMELL <b>Sympt</b> NO <b>om Pre</b> <b>sent:</b>	Initial Entry

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

**4.f Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW LOSS OF TAST E OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Sympt</b> NEW OR IN <b>oms:</b> CREASED S ORE THROA T <b>Sympt</b> NO <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

**4.g Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NEW OR INCREASE D SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> DIARR HEA <b>Symptom P</b> YES <b>resent:</b>	Initial Entry

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

**4.h Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> VOMIT ING <b>Symptom P</b> NO <b>resent:</b>	Initial Entry

090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1007

**Subject No:** 10071620

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

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assay Code and Description:**

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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
Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:37 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** MICROBIOLOGY SPECIMEN - 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)

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Feb-16-2021 08:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - 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
Feb-16-2021 08:57:02 (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
Feb-16-2021 08:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

### 3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 13:06:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-16-2021 11:59:02	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 1: Answered	nasal swab not collected;



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/05/2021

**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - 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

(UTC-05:00) Eastern Time (US & Canada)				protocol deviation submitted
Feb-16-2021 11:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please a nasal swab should be collected ASAP
Feb-16-2021 08:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Feb-16-2021 08:57:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> subject not able	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1007

**Subject No:** 10071620

**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:** ---

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-16-2021 08:57:16 (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
Feb-16-2021 08:57:16 (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
Feb-16-2021 08:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -

Unscheduled Visit on Feb/05/2021

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**Site No:** 1007

**Subject No:** 10071620

**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  
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Date	Location	User	Value	Reason
Feb-16-2021 08:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> subject did not come in	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021**Form Version:** 14-Jan-2021 02:24**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION - 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.a*

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Type of Practi</b> SPEC <b>tioner:</b> IALIS T <b>Occurrence of NO</b> <b>Visits or Cont</b> <b>acts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject Initials:** ---

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

**1.b**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERG ENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**1.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

**1.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**1.c**

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Site No:** 1007

**Subject No:** 10071620

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

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
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**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Type of Pr</b> PRIMAR <b>actitioner:</b> Y CARE PHYSICI AN <b>Occurren</b> NO <b>ce of Visit</b> <b>s or Conta</b> <b>cts:</b>	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> PRIMARY CARE PH YSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

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**Header Text:** c4591001

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**Site No:** 1007

**Subject No:** 10071620

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

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
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**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1007) Cincinnati Children's Hospital Medical  
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**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Type of Prac</b> URGE <b>titioner:</b> NT CA RE <b>Occurrence</b> NO <b>of Visits or C</b> <b>ontacts:</b>	Initial Entry

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021**Form Version:** 14-Jan-2021 02:24**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION - 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

Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Type of Pr TELEPH</b> <b>actioner: ONE CO</b> <b>NSULTA</b> <b>TION</b>  <b>Occurren NO</b> <b>ce of Visit</b> <b>s or Conta</b> <b>cts:</b>	Initial Entry
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***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> TELEPHONE CONS ULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

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

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** HEALTH CARE UTILIZATION - 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

Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OT HE R <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 08:58:58	ACV0PFEINFP6000	Laura Pace	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** HEALTH CARE UTILIZATION - 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

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

(b) (4)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ILLNESS DETAILS - 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. Category of Clinical Event:**

Date	Location	User	Value	Reason
Feb-16-2021 08:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID- 19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Feb-16-2021 08:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-16-2021 08:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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-29-2021 09:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

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

**Form Status:**

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

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Feb-01-2021 16:11:17 (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:** 10071620

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

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

**Form Status:**

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

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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

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

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Date	Location	User	Value	Reason
Feb-18-2021 10:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Deleted	Changed Information
Feb-14-2021 21:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

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

**Form Status:**

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

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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**Site No:** 1007

**Subject No:** 10071620

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

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

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

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**1. Category:**

Date	Location	User	Value	Reason
Jan-29-2021 09:09:23 (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-29-2021 09:09:23 (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-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Vulvar boil	Initial Entry

**4. Start Date Time:**

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**Header Text:** c4591001

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**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT - 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
Jan-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/24/2021 UNK:UN K	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO End Date Time:  Jan/26/2021 UNK: UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-29-2021 09:09:23 (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;**

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**Site No:** 1007

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**Subject Initials:** ---

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

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*Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Jan-29-2021 09:09:23 (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-29-2021 09:09:23 (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
Feb-22-2021 18:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-09-2021 12:31:51	ACV0PFEINFP6000	auto query (autoquery)	Query 2: 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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				
Feb-09-2021 12:31:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s , this event is du e to:  OTHER  <i>If Other, specif y:</i>  Presumed sta ph infection	Changed Information
Feb-05-2021 10:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical With respect to MRSA, how diagnosed (ie cultured or other); was there a known MRSA exposure or prior MRSA event or risk factor for MRSA.
Feb-03-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

11:59:42 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		satisfies query
Feb-03-2021 07:35:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-03-2021 07:35:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER  <i>If Other, specify:</i>  Presumed MRSA	Changed Information
Feb-02-2021 18:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Other cause for event Vulvar boil is Infection; please specify bacterial/viral/yeast infection; with

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

				specific diagnosis if available
Jan-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Infection	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-05-2021 10:19:53	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Feb-04-2021 17:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 1: Answered	submitted to SAE report
Feb-03-2021 13:23:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you; please submit this information on AE 'vulvar boil' to SAE (#2021101980), as concurrent with the SAE and associated complaints including fever
Feb-03-2021 07:37:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 1: Answered	clindamycin 1% gel(antibacterial)
Feb-02-2021 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please specify if Con med is anti-bacterial, anti-viral,



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1007

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**Subject No:** 10071620

**Subject Initials:** ---

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

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

				anti-fungal, anti-inflammatory or other type of medication; oral/topical
Jan-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 09:09:23 (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-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

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**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT - 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
Jan-29-2021 09:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

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

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

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

**Subject Initials:** ---

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**1. Category:**

Date	Location	User	Value	Reason
Jan-29-2021 09:11:31 (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-29-2021 09:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-22-2021 18:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021	ACV0PFEINFP6000	Laura Pace	Query 1: Answer	updated SAE

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

10:43:15 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	ed	report; No previous abdominal pain/issues
Feb-05-2021 10:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Please submit a SAE safety update reporting the ABDOMINAL EXAMINATION findings at each of the 3 ER visits. Thank you.
Jan-29-2021 09:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Abdominal pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-29-2021 09:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/21/2021 UNK:UN K	Initial Entry

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

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

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

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

Date	Location	User	Value	Reason
Feb-14-2021 21:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO End Date Time:  Feb/9/2021 UNK: UNK	New Information
Jan-29-2021 09:11:31 (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-29-2021 09:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT - 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
Jan-29-2021 09:11:54 (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-29-2021 09:11:31 (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-29-2021 09:11:31 (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
Jan-29-2021 09:11:31	ACV0PFEINFP6000	Laura Pace	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

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

(b) (4)

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jan-29-2021 09:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 09:11:31 (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
Feb-14-2021 21:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Close d	Close Auto Query

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

Feb-14-2021 21:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERED/ RESOLVED	New Information
Feb-14-2021 21:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Abdominal pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-29-2021 09:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERING /RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 09:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry



**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, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-01-2021 16:11:17 (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
Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 18:38:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-22-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response

**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, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

18:37:53 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		satisfies query
Feb-15-2021 21:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-09-2021 10:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Feb-09-2021 10:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Feb-09-2021 10:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-09-2021 10:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> generalized Functional neurologic pain	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, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

Feb-08-2021 10:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical On review of the SAE report for Pain, an event of gastritis (related to gastritis) was mentioned, yet it does not appear in the AE CRF. Please review for safety and update AE log CRF accordingly.
Feb-07-2021 19:40:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	ClinQuery: Functional neurologic pain: please can you specify if this is localised or generalised? Thanks
Feb-05-2021 15:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-05-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Thank

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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

10:19:08 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		you for the premenarch history; please submit this to the SAE; in addition, please specify if there is any history of Abdominal Pain / complaints
Feb-04-2021 17:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Functional neurolo gic pain	Changed Information
Feb-04-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 1: Answered	The subject has not had onset of menses. The AE's of vulvar boil, abdominal pain, and generalized pain are, therefore, unrelated to menses
Feb-03-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin:

**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, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

19:14:07 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		please confirm if participant has/has not had onset of menses and whether AEs vulvar boil, abdominal pain, generalized pain were/were not associated with onset of menses. Thank you
Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> unspecified general ized pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-08-2021 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021	ACV0PFEINFP6000	Laura Pace	Query 1: Answered	corrected date

**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, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

17:42:16 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)		on SAE report
Feb-03-2021 22:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Visit 2 date & 2nd vaccination date are 20Jan21; however, SAE report reports 2nd VAX on 21Jan21 in Product information (narrative date is 20Jan21). Please review, and update Product Information as applicable.
Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/21/2021 UNK: UNK	Initial Entry

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

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

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry
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**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Feb-03-2021 09:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021	ACV0PFEINFP6000	auto query	Query 1: Candidate	For AE

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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

16:11:17 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		unspecified generalized pain: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Is this serious event associated with con genital anomaly or birth defect?  NO  Did this serious eve nt result in death?  NO  Did this serious eve nt require or prolon g hospitalization?  YES  Did this serious eve nt result in persisten	Initial Entry



**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, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

			t or significant disability/incapacity?  NO  Is this serious event life threatening?  NO  Other medically important serious event  NO	
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**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-01-2021 16:11:17 (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
Feb-09-2021 02:15:51 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

**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, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

Eastern Time (US & Canada)				
Feb-08-2021 07:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-08-2021 07:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unspecified	New Information
Feb-08-2021 06:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "If Not Related to study treatment(s), this event is due to is reported as "Other", however

**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, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

				specify is missing? kindly review and update.
Feb-04-2021 17:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER	Changed Information
Feb-01-2021 16:11:17 (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
Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

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

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT - 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

Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-01-2021 16:11:17 (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
Feb-04-2021 12:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERING/RES OLVING	New Information
Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RECOVERED/ NOT RESOLVED	Initial Entry

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

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**Header Text:** c4591001

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** ADVERSE EVENT REPORT - 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

Date	Location	User	Value	Reason
Feb-01-2021 16:11:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-03-2021 09:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4) (b) (4)	<b>Data Entry:</b> 2021101980	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (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
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 10:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Closed	Response satisfies query
Feb-22-2021	ACV0PFEINFP6000	Laura Pace	Query 1: Answered	per sub I

**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:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

06:33:16 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)		Gastritis is not related to a COVID illness. It is related to ibuprofen intake
Feb-18-2021 12:00:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Opened	GPD CLIN: Per section 8, please confirm if gastritis is possibly related to COVID illness and perform swab collection as soon as possible Symptoms of COVID should be solely documented in SOD covid illness folder, if confirmed. Thank you.
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> Gastritis	Initial Entry

**4. Start Date Time:**

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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

Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/30/2021 UNK:UN K	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (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
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;  
Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (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
Feb-09-2021 12:30:37 (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
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  CONCOMITANT DRUG TREATMENT	Initial Entry

**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:** 10071620

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (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
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090177e196ae30aa\Final\On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERING/RESO LVING	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-09-2021 12:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Deleted**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

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

[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-14-2021 21:03:21 (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
Feb-14-2021 21:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 19:31:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query

Feb-18-2021 09:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 1: Answered	deleting
Feb-16-2021 11:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued: Opened	Clin: Per Prot Sect 8.3.7., COVID-19 listed symptom DIARRHEA does not qualify as AE and please should be documented only on the COVID Illness SOD CRF form and should not be captured on the AE CRF form
Feb-16-2021 08:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Query 1: Answered	completed
Feb-15-2021 15:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per Prot Sect 8.1., COVID-19 listed symptom DIARRHEA should please trigger a potential COVID-19 Visit irrespective of perceived etiology or clinical

				significance, captured on the SOD form and a NASAL SWAB collected ASAP
Feb-14-2021 21:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> diarrhea	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-14-2021 21:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Feb/5/2021 UNK:UN K	Initial Entry

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

Date	Location	User	Value	Reason
Feb-14-2021 21:03:21 (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
Feb-14-2021 21:03:21 (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 medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Feb-14-2021 21:03:21 (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
Feb-14-2021 21:03:21 (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
Feb-14-2021 21:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  CONCOMITANT DRUG TREATMENT	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

Feb-14-2021 21:03:21 (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
Feb-14-2021 21:03:21 (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
Feb-14-2021 21:03:21 (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
Feb-14-2021 21:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERING/RESO LVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-14-2021 21:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry



**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:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (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
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> contact dermatitis bilat eral arms	Initial Entry

**4. Start Date Time:**

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Feb/12/2021 UNK:UN K	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (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
Feb-24-2021 07:08:21 (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**

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1007

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

**Subject No:** 10071620

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (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
Feb-24-2021 07:08:21 (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
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to stud y treatment(s), this ev ent is due to:  OTHER  <i>If Other, specify:</i>	Initial Entry

**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:** 10071620

**Subject Initials:** ---

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

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

suspected reaction to tape

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

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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

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

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> RECOVERING/RESO LVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 07:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled  
Visit on Jan/21/2021**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071620**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[Back to Form](#)*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-26-2021 12:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Jan/21/2021	Initial Entry

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled  
Visit on Jan/21/2021**Form:** UNPLANNED VISIT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical  
Center**Subject No:** 10071620**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)***1. Assessments***

Date	Location	User	Value	Reason
Jan-27-2021 08:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-27-2021 03:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Jan-26-2021 12:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Jan/21/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** UNPLANNED 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

Jan-26-2021  
12:15:29  
(UTC-05:00)  
Eastern Time (US  
& Canada)

ACV0PFEINFP6000

Laura Pace  
(b) (4)

**Data Entry:**  
CONTACT OUTCO  
ME

Initial Entry



**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled  
Visit on Jan/21/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1007**Subject No:** 10071620**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - 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. Contact Type:**

Date	Location	User	Value	Reason
Jan-27-2021 08:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Jan-27-2021 08:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-27-2021 08:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> YES Date of Contact:  Jan/21/2021  Contact Outcome:  VISIT NOT ARR ANGED, UNABL E TO ATTEND	Changed Information

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Jan/21/2021

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

**Site No:** 1007

**Subject No:** 10071620

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

**Form:** CONTACT OUTCOME - UNPLANNED - 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

Jan-27-2021 08:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Contact Outcome" is missing.
Jan-27-2021 08:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b><u>Data Entry:</u></b> YES Date of Contact:  Jan/21/2021	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1007

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

**Subject No:** 10071620

**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
Feb-18-2021 18:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> Feb/18/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-18-2021 18:39:26 (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
Feb-18-2021 18:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071620**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[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Feb-18-2021 18:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-30-2020 11:14:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Dec-30-2020 11:08:57 (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
Feb-18-2021 18:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/18/2021	Initial Entry
Dec-30-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071620

**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

11:14:42 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Dec/30/2020	
Dec-30-2020 11:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b><u>Data Entry:</u></b> Dec/30/2020	Initial Entry

090177e196ae30aa\Final\Final On: 01-Apr-2021 04:12 (GMT)