

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/17/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10071581]
2.	Birth Date:	(b) (6)/2005
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Dec/17/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[ADHD]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Migraine]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/17/2020
2.	Weight:	[64.8]
3.	Unit:	kg
4.	Height:	[175.0]
5.	Unit:	cm
6.	Body Mass Index:	[21.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Dec/17/2020
2.	Randomization Number:	[22928]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP90YG]
5.b	Sample ID	[BP90YH]
5.c	Sample ID	[BMNR24]

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP90YL]
5.b	Sample ID	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/17/2020 15:49
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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/7/2021
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRB8JW]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/7/2021 15:49
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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

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

Subject No: 10071581 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

Subject No: 10071581 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

Subject No: 10071581 **Subject Initials:** ---

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

Subject No: 10071581 **Subject Initials:** ---

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071581**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRB93H]
5.b	Sample ID	[BRB93J]
5.c	Sample ID	[BNWMY1]

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 30-Apr-2021 01:47

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

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

Subject Initials: ---

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

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071581**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

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

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

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

Subject No: 10071581 **Subject Initials:** ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

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

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

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

Subject No: 10071581 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 30-Apr-2021 01:41

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

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

Subject No: 10071581 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/18/2021
----	--------------	--

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**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:** 10071581**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BV03DL]
5.b	Sample ID	[BV03DM]
5.c	Sample ID	[BS289D]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/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	[BV03DR]
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/01/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Surveillance Visit

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

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/01/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071581**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA02042]
-----	-----------	-----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/13/2021

Form Version: 14-Jan-2021 02:22

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Apr/13/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

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

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/13/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1007**Subject No:** 10071581**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/13/2021
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	[AA02034]
-----	-----------	-----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Apr/27/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Apr/27/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

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

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Apr/27/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1007**Subject No:** 10071581**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/27/2021
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	[AA02040]
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Header Text: c4591001

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

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

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

Subject No: 10071581 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

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

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

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Appendicitis	Mar/10/2021 UNK:UNK	NO End Date Time: Mar/29/2021 UN K:UNK	Repeating Pages
2.	ADVERSE EVENT	2	injection site pain	Jun/15/2021 UNK:UNK	NO End Date Time: Jun/16/2021 UNK :UNK	Repeating Pages
3.	ADVERSE EVENT	3	fatigue	Jun/15/2021 UNK:UNK	NO End Date Time: Jun/16/2021 UNK :UNK	Repeating Pages
4.	ADVERSE EVENT	4	generalized muscle aches	Jun/15/2021 UNK:UNK	NO End Date Time: Jun/16/2021 UNK :UNK	Repeating Pages

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Appendicitis]
4.	Start Date Time:	Mar/10/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/29/2021 UNK:UNK
6.	Toxicity Grade:	3

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

7.	<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? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event 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>	<p>NO</p>
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: OTHER</p> <p>If Other, specify: [Infection]</p>

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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?:	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	[2021290714]

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[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)	[injection site pain]
4.	Start Date Time:	Jun/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jun/16/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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	[]

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[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)	[fatigue]
4.	Start Date Time:	Jun/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jun/16/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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	[]

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[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)	[generalized muscle aches]
4.	Start Date Time:	Jun/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jun/16/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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	[]

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Medication Error

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	<p>Medication:</p> <p>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).</p>	[]
5.	Date:	//

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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?	

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Radiation Treatment

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	May/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained May/24/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	May/24/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BTDMS1]
5.b	Sample ID	[BS2945]
5.c	Sample ID	[BS2946]

Header Text: c4591001

Visit: V101_VAX3

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BTDMS0]
-----	-----------	----------

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	May/24/2021 12:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jun/14/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jun/14/2021
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	[BTDMXW]
-----	-----------	----------

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jun/14/2021 11:23
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jul/13/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jul/13/2021
3.	Comments:	[]

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Jul/13/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/4/2021

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Aug-27-2021 13:41:42 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-17-2020 15:29:07 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	May-24-2021 12:45:54 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Aug-27-2021 13:41:42 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Laura Pace	N/A	Mar-29-2021 16:26:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Frenck	Approved	Mar-19-2021 16:07:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

Haley Muth	N/A	Mar-18-2021 13:43:25 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Frenck	Approved	Mar-17-2021 21:25:23 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

Affidavit:

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

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

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Dec-17-2020 15:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 15:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Dec-17-2020 15:21:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Dec/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Dec-17-2020 15:20:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 10071581	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-17-2020 15:20:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: (b) (6) 2005	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-17-2020 15:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Dec-17-2020 15:21:11	ACV0PF EINFP60	Laura Pace	Data Entry: NOT HISPANIC OR LATIN	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Dec-17-2020 15:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 15:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Dec/17/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Dec-17-2020 15:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Dec/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-17-2020 15:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-17-2020 15:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Dec-17-2020 15:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: ADHD Start Date: UNK/UNK /2012 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Dec-17-2020 15:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 15:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: ADHD	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

1.a Start Date:

Date	Location	User	Value	Reason
Dec-17-2020 15:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: UNK/UNK/2012	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Dec-17-2020 15:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Dec-17-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Migraine Start Date: UNK/UNK/ 2018 Ongoing: YES	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Dec-17-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Migraine	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Dec-17-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: UNK/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Dec-17-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-17-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Dec/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 64.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Dec-17-2020	ACV0PF	Laura	Data Entry:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

16:00:41 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	Pace (b) (4)	175.0	
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5. Unit:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 21.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Record Identifier: Temperature: 37.0 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Dec-17-2020 16:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Dec-17-2020 16:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Dec/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-17-2020 16:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 22928	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-17-2020 16:04:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 16:04:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 16:29:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 16:04:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				review and correct as appropriate.
Dec-17-2020 16:04:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-17-2020 16:29:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP90YG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:29:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP90YG	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Dec-17-2020 16:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP90YH	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP90YH	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 16:29:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BMNR24	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:29:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: BMNR24	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-17-2020 16:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 16:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 16:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-17-2020 16:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection.

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				Please review and correct as appropriate.
Dec-17-2020 16:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 16:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-17-2020 16:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-17-2020 16:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP90YL	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP90YL	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-17-2020 16:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Dec-17-2020 16:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BP90YH	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-17-2020 16:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BP90YH	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-05-2021 00:28:41	ACV0PF EINFP60	(b) (4), (b) (6)	Query 1: Closed	Query closed per site response.

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		
Jan-04-2021 07:29:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 1: Answered	confirmed subject had a faulty thermometer; subject has now has new thermometer
Dec-22-2020 03:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per eDiary records, e-Diary Temperature value(s) recorded is < 94 F (34.4 C). Please confirm if the thermometer recording from subject or the entry is appropriate. Thanks.
Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Dec/17/2020 15:49	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-17-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Dec-17-2020 16:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FO R THIS SUBJECT	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-07-2021 15:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Jan/7/2021	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, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[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-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: FE V ER Were fever or systemic symptoms present on th e last day the Subject D iary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: FEVER	Initial Entry

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

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: FA TI GU E Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed? :	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: CH IL LS Were fever or systemic N symptoms present on th O e last day the Subject D iary was completed?:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: VO MIT ING Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed? :	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed ?:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NEW OR WORSENERD MUS CLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT P AIN Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed? :	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NEW OR WORSENERD JOIN T PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry

5.a

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Injection Site Reaction RE : DN ES S Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38	ACV0PF	Laura	Data Entry:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	Laura Pace (b) (4)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	Laura Pace (b) (4)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

			E Were injection site reactions present on the last day the Sub ject Diary was com pleted?:	
--	--	--	--	--

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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-07-2021 15:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jan-07-2021 15:07:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Jan/7/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-07-2021 15:07:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Record Identifier: Temperature: 37.0 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-07-2021 15:07:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Jan-07-2021 15:07:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 37.0	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Jan-07-2021 15:07:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jan-07-2021 15:07:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-07-2021 15:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-07-2021 15:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-07-2021 16:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 15:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Jan-07-2021 15:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES Date of Collection: Jan/7/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-07-2021 16:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRB8JW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 16:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRB8JW	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Jan/7/2021 15:49	Initial Entry

5. Anatomical Location:

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Jan-07-2021 16:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES	Initial Entry
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 14:26:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Feb/4/2021	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

[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
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: FE V ER Were fever or systemic N symptoms present on th O e last day the Subject D iary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: FEVER	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: FA TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

2.b Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed? :	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

2.c Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: CH IL LS Were fever or systemic N symptoms present on th O e last day the Subject D iary was completed?:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

2.d Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: VO MIT ING Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed? :	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

2.e Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

2.f Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NEW OR WORSENE D MUS CLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Symptom:: NEW O R WOR SENE D	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

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

2.h Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

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

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Injection Site Reaction RE :: DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: REDNESS	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

Time (US & Canada)				
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Injection Site Reaction: PAIN AT INJ ECTIO N SIT E Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 14:27:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-04-2021 14:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-04-2021 14:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 15:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 14:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10071581 Subject Initials: ---

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

				review and correct as appropriate.
Feb-04-2021 14:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES Date of Collection: Feb/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 15:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRB93H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 15:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRB93H	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

Feb-04-2021 15:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRB93J	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 15:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRB93J	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 15:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BNWMY1	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 15:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: BNWMY1	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-18-2021 13:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	Data Entry: Mar/18/2021	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Mar-18-2021 13:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	Data Entry: OBTAINED Date Written Consent Obtai ned Mar/18/2021	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-18-2021 13:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-18-2021 13:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-18-2021 14:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-18-2021 13:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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

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

Subject No: 10071581 **Subject Initials:** ---

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

				review and correct as appropriate.
Mar-18-2021 13:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	Data Entry: YES Date of Collection: Mar/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-18-2021 14:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BV03DL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-18-2021 14:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BV03DL	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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

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

Subject No: 10071581 **Subject Initials:** ---

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

Mar-18-2021 14:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BV03DM	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Mar-18-2021 14:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BV03DM	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-18-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BS289D	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -
Unscheduled 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: 10071581 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Mar-18-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: BS289D	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-18-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-18-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-18-2021 14:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-18-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL
Unscheduled SWAB - eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

				review and correct as appropriate.
Mar-18-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Haley Muth (b) (4)	Data Entry: YES Date of Collection: Mar/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-18-2021 14:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BV03DR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-18-2021 14:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BV03DR	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-04-2021 14:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Feb/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-04-2021 14:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/01/2021

Form Version: 14-Jan-2021 02:22

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Apr-02-2021 11:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/1/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Apr-02-2021 11:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK2	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/01/2021

Form Version: 10-Oct-2020 15:57

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-02-2021 11:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-02-2021 11:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-02-2021 11:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-02-2021 11:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/01/2021

Form Version: 10-Oct-2020 15:57

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

				review and correct as appropriate.
Apr-02-2021 11:17:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-02-2021 11:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA02042	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-02-2021 11:18:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA02042	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/13/2021

Form Version: 14-Jan-2021 02:22

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Apr-14-2021 10:40:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/13/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Apr-14-2021 10:40:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK4	Initial Entry

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/13/2021

Form Version: 10-Oct-2020 15:57

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-14-2021 10:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-14-2021 10:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-14-2021 10:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-14-2021 10:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/13/2021

Form Version: 10-Oct-2020 15:57

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

				review and correct as appropriate.
Apr-14-2021 10:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-14-2021 10:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA02034	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-14-2021 10:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA02034	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Apr/27/2021

Form Version: 14-Jan-2021 02:22

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Apr-28-2021 11:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/27/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Apr-28-2021 11:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK6	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Apr/27/2021

Form Version: 10-Oct-2020 15:57

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-28-2021 11:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-28-2021 11:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-28-2021 11:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-28-2021 11:32:17 (UTC-05:00)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on Apr/27/2021

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Apr-28-2021 11:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/27/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-28-2021 11:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: AA02040	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-28-2021 11:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: AA02040	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
May-24-2021 10:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: May/4/2021	Transcription Error
May-24-2021 10:00:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: May/12/2021	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

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

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

Subject No: 10071581 **Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
May-24-2021 10:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national r ecommendations and confi rmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-24-2021 21:56:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 3: Closed	Query closed; will follow for requested VAX 3 & 4 dates information.
Aug-24-2021 16:44:20 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 3: Answered	faxed update 24aug2021

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
Aug-24-2021 10:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	Clinical - please submit a SAE update (#2021290714) to report VAX3 and VAX4 dates
Apr-20-2021 20:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 2: Closed	Response satisfies query
Apr-01-2021 13:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4) [REDACTED]	Query 2: Answered	SAE report updated
Mar-27-2021 12:10:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	Clinical - Subject has past Med hx of migraines and ADHD; however, SAE report does not list any Con Meds for these conditions. Please confirm NO con meds; if subject has

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				medications please submit to SAE report Con Meds section
Mar-17-2021 20:38:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-17-2021 19:59:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 1: Answered	per mother subject was admitted to hospital and met the criteria to try antibiotics instead of surgery. He did 24 hours of IV antibiotics and started oral antibiotics
Mar-17-2021 18:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm that appendicitis was the diagnosis at discharge given SAE narrative of 24 hr hospitalization and discharge

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				with no surgical intervention.
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Appendicitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Apr-21-2021 05:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	SDB updated
Apr-20-2021 20:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Apr-19-2021 06:36:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Candi date	Pending SDB update
Apr-15-2021 09:40:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 2: Answered	re-faxing today

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
Apr-15-2021 04:14:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON:As per the DSU- We have not received a follow-up report on 30Mar2021. A new SAE report form is needed to make any changes to the Safety Database
Apr-14-2021 05:07:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Candidate	For PSSR review
Apr-12-2021 15:20:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 2: Answered	sub pi received email confirmation on 30mar2021 with this update
Apr-12-2021 07:58:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Opened	Per CT-HUB: Please find below screen shot of the latest FU source received on 17Mar2021. Onset date reported as 11-Mar-2021. A

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				new SAE form is needed to make any changes to the Safety Database. Please submit a follow up SAE form to update onset date
Apr-07-2021 02:10:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Candi date	Pending SDB update
Apr-06-2021 11:11:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 2: Answered	the updated SAE report was sent on 30mar2021
Apr-05-2021 06:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2021290714 ,onset date was recorded as 11Mar2021 in Safety database however, recorded as 10Mar2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				submit a follow-up SAE form.
Mar-30-2021 14:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-30-2021 14:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Mar/10/2021 UNK:UNK	Changed Information
Mar-27-2021 12:08:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Clinical - Start date is 11Mar21; however, SAE reports subject had 1 day Abd pain on arrival to ER on 11Mar21. In Vaccine study, SAE start date is day event starts; not day it meets serious criteria (item 11 in vaccine SAE instruct); please review
Mar-16-2021	ACV0PF	Laura Pace	Data Entry:	Transcription

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

17:37:17 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4)	Mar/11/2021 UNK:UNK	Error
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Mar/3/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Apr-20-2021 20:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-30-2021 14:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
Mar-30-2021 14:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO End Date Time: Mar/29/2021 UNK:UNK	New Information

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Mar-27-2021 12:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Clinical - please review event for END date; if END date reached also submit to SAE
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-29-2021	ACV0PF	Laura Pace	Data Entry:	Changed

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

16:26:41 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4)	<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>	Information
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Mar-17-2021 07:42:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	For AE Appendicitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

			Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	
--	--	--	--	--

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-17-2021 20:39:35 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
Mar-17-2021 19:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-17-2021 19:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Infection	Initial Entry
Mar-17-2021 18:47:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please complete item 9. in alignment with SAE form submitted

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-17-2021 20:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-17-2021 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 1: Answered	subject did not have surgery
Mar-17-2021 18:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm that patient did/did not require surgical intervention for diagnosis of appendicitis.
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Apr-21-2021 05:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	SDB updated

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Apr-19-2021 06:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued: Candidate	Pending SDB update
Apr-15-2021 09:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 2: Answered	re-faxing today
Apr-15-2021 04:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued: Opened	SAE RECON: As per the DSU- We have not received a follow-up report on 30Mar2021. A new SAE report form is needed to make any changes to the Safety Database
Apr-14-2021 05:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued: Candidate	For PSSR review
Apr-12-2021 15:34:27 (UTC-05:00) Eastern Time	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 2: Answered	sub pi received a confirmation email on 30mar2021 with update

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Apr-12-2021 07:57:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Opened	Per CT-HUB: For AER# 2021290714, it was provided as recovering on latest FU. A new SAE form is needed to make any changes to the Safety Database. Please submit a follow up form to update outcome in Safety DB.
Apr-07-2021 02:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Candidate	pending SDB update
Apr-06-2021 11:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Query 2: Answered	the updated SAE report was sent On 30mar2021
Apr-05-2021 06:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021290714,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Mar-30-2021	ACV0PF	auto query	Query 1: Closed	Close Auto Query

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

14:43:51 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(autoquery)		
Mar-30-2021 14:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: RECOVERED/ RESOLVED	New Information
Mar-30-2021 14:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	For AE Appendicitis: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: RECOVERING /RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-16-2021 17:34:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-17-2021 07:42:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2021290714	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, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47	ACV0PF EINFP60	Laura Pace	Data Entry: Jun/15/2021 UNK:UNK	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

00

(b) (4)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO End Date Time: Jun/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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
Jun-17-2021	ACV0PF	Laura	Data Entry:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

09:00:47 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	Pace (b) (4)	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
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jun-17-2021 10:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jun-17-2021 09:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10	ACV0PF EINFP60	Laura Pace	Data Entry: Jun/15/2021 UNK:UNK	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

00

(b) (4)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO End Date Time: Jun/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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
Jun-17-2021	ACV0PF	Laura	Data Entry:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

09:02:10
(UTC-05:00) Eastern
Time (US & Canada)

EINFP60
00

Pace
(b) (4)

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.

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jun-17-2021 10:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jun-17-2021 09:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: generalized muscle aches	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08	ACV0PF EINFP60	Laura Pace	Data Entry: Jun/15/2021 UNK:UNK	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

00

(b) (4)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO End Date Time: Jun/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: 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
Jun-17-2021	ACV0PF	Laura	Data Entry:	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

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Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

09:29:08 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	Pace (b) (4)	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
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jun-17-2021 10:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jun-17-2021 09:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
May-24-2021 10:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: May/12/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
May-24-2021 10:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
May-24-2021 12:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/24/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - 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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
May-24-2021 12:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained May/24/2021	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - 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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
May-24-2021 12:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: May/24/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
May-24-2021 12:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
May-24-2021 12:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
May-24-2021 12:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-24-2021 12:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-24-2021 12:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-24-2021 12:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				review and correct as appropriate.
May-24-2021 12:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/24/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-24-2021 12:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BTDMS1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-24-2021 12:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BTDMS1	Initial Entry

5.b

Date	Location	User	Value	Reason
May-24-2021 12:43:03 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BS2945	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)

5.b Sample ID

Date	Location	User	Value	Reason
May-24-2021 12:43:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BS2945	Initial Entry

5.c

Date	Location	User	Value	Reason
May-24-2021 12:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BS2946	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
May-24-2021 12:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BS2946	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
May-24-2021 12:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-24-2021 12:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-24-2021 12:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-24-2021 12:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				review and correct as appropriate.
May-24-2021 12:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: May/24/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-24-2021 12:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BTDMS0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-24-2021 12:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BTDMS0	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
May-24-2021 12:46:32	ACV0PF EINFP60	Laura Pace	Data Entry: May/24/2021 12:07	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
May-24-2021 12:46:32	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
May-24-2021 12:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jun-14-2021 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Jun/14/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-14-2021 10:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-14-2021 10:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-14-2021 10:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-14-2021 10:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

				correct as appropriate.
Jun-14-2021 10:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jun/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-14-2021 10:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BTDMXW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-14-2021 10:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BTDMXW	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071581

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): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Yislain Villalona (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00)	ACV0PF EINFP60 00	Yislain Villalona (b) (4)	Data Entry: Jun/14/2021 11:23	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Yislain Villalona (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

9. Unit:

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jun-14-2021 13:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Yislain Villalona (b) (4)	Data Entry: YES	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jul-14-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Jul/13/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - 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: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Jul-14-2021 09:36:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jul-14-2021 09:36:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: YES Date of Contact: Jul/13/2021	Initial Entry

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jul-14-2021 09:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Jul/13/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-14-2021 09:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-14-2021 09:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Feb-04-2021 14:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Dec-17-2020 16:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Dec-17-2020 15:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-04-2021 14:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Feb/4/2021	Initial Entry
Dec-17-2020 16:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Dec/17/2020	Initial Entry

090177e19891a038\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071581

Subject Initials: ---

Generated By: (b) (4)

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

Dec-17-2020 15:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Dec/17/2020	Initial Entry
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071581

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Mar-15-2021 17:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Laura Pace (b) (4)	Data Entry: Click Here to Enable	Initial Entry