

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[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 Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Demography**

1.	Subject ID	[10071585]
2.	Birth Date:	(b) (6) 2008
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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: 10071585

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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 _____
----	----------------------------------------	-------------------------

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 15-Sep-2020 21:52**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** DISPOSITION - SCREENING**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[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:** 10071585**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[ADHD, predominantly inattentive type]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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:** 10071585**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Dec/17/2020
2.	Weight:	[89.4]
3.	Unit:	kg
4.	Height:	[168.0]
5.	Unit:	cm
6.	Body Mass Index:	[31.7]

Vital Signs Details

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Dec/17/2020
2.	Randomization Number:	[23094]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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	[BP90YW]
5.b	Sample ID	[BP90YX]
5.c	Sample ID	[BMNR28]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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	[BP90Z3]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

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 16:27
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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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 Version: 10-Dec-2020 02:30

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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?	YES Ongoing? NO Stop Date: Dec/25/2020

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:27**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Vital Signs**

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

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

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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	[BRB8K1]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

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 15:58
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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

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

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

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

Subject No: 10071585 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

[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, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[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

090177e196b72782\Final\On: 06-Apr-2021 19:05 (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, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (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, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585 **Subject Initials:** ---**Generated By:** (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36[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	[BRB941]
5.b	Sample ID	[BRB942]
5.c	Sample ID	[BNWMY9]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V4_MONTH6_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V5_MONTH12_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V6_MONTH24_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 20-Feb-2021 02:17**Site No:** 1007**Subject No:** 10071585**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):** 06-Apr-2021 15:36**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:	[]
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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:** 10071585**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 10071585**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):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** HEALTH CARE UTILIZATION**Form Version:** 20-Feb-2021 02:19**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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?	
----	----------------------------------------------------------------------	--

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 06-Jul-2020 21:52

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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: 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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	Headache	Dec/17/2020 21:00	NO End Date Time: Dec/25/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	hives; trunk, abdomen, back	Jan/16/2021 UNK:UNK	YES	Repeating Pages

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Deleted**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

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

[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Dec/17/2020 21:00
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/25/2020 UNK:UNK
6.	Toxicity Grade:	+

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36***** THIS REPEATING FORM HAS BEEN DELETED *****

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

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Deleted**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36***** THIS REPEATING FORM HAS BEEN DELETED *****

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

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[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)	[hives; trunk, abdomen, back]
4.	Start Date Time:	Jan/16/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	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 Version: 17-Jul-2020 21:54

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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	[]

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[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.	Date:	//

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS -
PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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?	

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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?	

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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

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

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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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: 10071585 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 06-Apr-2021 15:36

Unplanned Assessments

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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

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:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** VITAL SIGNS - TEMP**Form Version:** 20-Feb-2021 02:16**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Vaccination**

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Contact Outcome

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

Header Text: c4591001

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

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Informed Consent - Asymptomatic Surveillance

1. Consent Was:

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[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:	[]

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

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

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 10-Dec-2020 02:27

Form Status: Not Started

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[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, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Dec-17-2020 15:51:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (b) (4)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001**Visit:** COHORT_SELECTION**Form:** COHORT SELECTION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:31**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Dec-17-2020 15:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 15:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Consent Was:

Date	Location	User	Value	Reason
Dec-17-2020 15:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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: 10071585

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Subject ID

Date	Location	User	Value	Reason
Dec-17-2020 15:50:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10071585	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-17-2020 15:49:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 2008	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-17-2020 15:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: MALE	Initial Entry

4. Ethnicity:

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

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Dec-17-2020 15:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NOT HISPANIC OR L ATINO(A) OR OF SP ANISH ORIGIN	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------	------------------------------------------------------------------------------	---------------

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

Date	Location	User	Value	Reason
Dec-17-2020 15:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: WHITE	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Dec/17/2020	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Dec-17-2020 16:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-17-2020 16:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-17-2020 16:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Dec-17-2020 16:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 1 H Num ber: Medical ADHD, pred History ominantly in Term: attentive typ e Start D UNK/UNK/ ate: 2018 Ongoin YES g:	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Dec-17-2020 16:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Dec-17-2020
16:35:47
(UTC-05:00)
Eastern Time (US
& Canada)

ACV0PFEINFP6000

Laura
Pace
(b) (4)

Data Entry:
ADHD, predominantly
inattentive type

Initial Entry

1.a Start Date:

Date

Location

User

Value

Reason

Dec-17-2020
16:35:47
(UTC-05:00)
Eastern Time (US
& Canada)

ACV0PFEINFP6000

Laura
Pace
(b) (4)

Data Entry:
UNK/UNK/2018

Initial Entry

1.a Ongoing:

Date

Location

User

Value

Reason

Dec-17-2020
16:35:47
(UTC-05:00)
Eastern Time (US
& Canada)

ACV0PFEINFP6000

Laura
Pace
(b) (4)

Data Entry:
YES

Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Dec-17-2020 16:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Dec/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: 89.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: kg	Initial Entry

4. Height:

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: 168.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Record Id 1	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Eastern Time (US & Canada)			ntifier:: Temperatur 36.9 e: Temperatur C e Unit: Temperatur ORAL e Location:: CAVIT Y	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<u>Data Entry:</u> C	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------	--------------------------------	---------------

7.a Temperature Location:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Randomization Date :

Date	Location	User	Value	Reason
Dec-17-2020 16:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Dec/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-17-2020 16:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: 23094	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Dec-17-2020 16:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 16:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 16:35:43	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-17-2020 16:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collecti on: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-17-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP90Y D: W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP90YW	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.b

Date	Location	User	Value	Reason
Dec-17-2020 16:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP90Y D: X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP90YX	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 16:36:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BMNR D: 28	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.c Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:36:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNR28	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Dec-17-2020 16:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 16:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 16:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 16:35:20	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-17-2020 16:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collecti on: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-17-2020 16:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP90Z D: 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP90Z3	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Dec/17/2020 16:27	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 16:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Dec-17-2020 16:50:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: YES - REACTOGENI CITY E-DIARY COL LECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-07-2021 15:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Jan/7/2021	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
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Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: FA TI G U E Were fever or sys N temic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
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Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.b Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-13-2021 07:54:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: HEADACHE	New Information

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Dec/25/2020	
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<u>Data Entry:</u> Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? ? YES ES	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical
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Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.c Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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-13-2021 14:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-13-2021 07:54:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answer ed	New Information
Jan-13-2021 07:54:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: YES Ongoing? NO Stop Date:	New Information

Header Text: c4591001

Visit: V2_VAX2_L

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Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
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Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Dec/25/20 20	
Jan-13-2021 05:05:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	eDiary: Per Diary records, 'HEADACHE' reported post Vaccination 1 is not ongoing through Vaccination 2. Please reconcile and consider to update stop date here. Else, clarify in query response. Thanks.
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: YES Ongoing? YES	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: C HI	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: VO MI TI NG Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
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Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
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Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.f

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<u>Data Entry:</u> Symptom:: DI AR RH EA Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.f Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY -
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Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever or NO systemic sym ptoms presen t on the last d ay the Subjec t Diary was c ompleted?:	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.h Symptom:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
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Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------	----------------------------	---------------

5.a

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Injection Site Reaction: REDNESS Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: REDNESS	Initial Entry

090177e196b72782\Final\On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTIO N SI TE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Were injection NO site reactions p resent on the l ast day the Su bject Diary wa s completed?:	
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-07-2021 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 19:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date:

Date	Location	User	Value	Reason
Jan-07-2021 15:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Jan/7/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-07-2021 15:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Record Identifier:: 1 Temperature: 37.1 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-07-2021 15:29:04 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: 1	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Eastern Time (US
& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Jan-07-2021 15:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: 37.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-07-2021 15:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jan-07-2021 15:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-07-2021 15:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-07-2021 15:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-07-2021 16:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 15:29:16	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-07-2021 15:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 16:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRB8 D: K1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 16:18:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRB8K1	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Jan/7/2021 15:58	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 16:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 15:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Feb/4/2021	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[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 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: FA TI G U E Were fever or sys N temic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.b Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50	ACV0PFEINFP6000	Laura Pace	Data Entry: Symptom:: C	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36(UTC-05:00)
Eastern Time (US
& Canada)

(b) (4)

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

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: VO MI TI NG Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.f

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	<u>Data Entry:</u> Symptom:: DI AR RH EA Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.f Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

			Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
--	--	--	---------------------------------------------------------------------------------------------------------------------------	--

2.g Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Feb-04-2021
15:45:50
(UTC-05:00)
Eastern Time (US
& Canada)

ACV0PFEINFP6000

Laura
Pace
(b) (4)

Data Entry:

Symptom:: NEW
OR W
ORSE
NED J
OINT
PAIN

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

Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

2.h Symptom:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: LEFT	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------	----------------------------	---------------

5.a

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Injection Site Reaction: REDNESS Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: REDNESS	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTIO N SI TE	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-04-2021 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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 15:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Feb-04-2021 15:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-04-2021 15:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 16:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 15:45:06	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36(UTC-05:00)
Eastern Time (US
& Canada)Yes, however
no barcodes
are entered.
Please review
and correct as
appropriate.Feb-04-2021
15:45:06
(UTC-05:00)
Eastern Time (US
& Canada)

ACV0PFEINFP6000

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 16:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRB94 D: 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 16:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRB941	Initial Entry

5.b

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-04-2021 16:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRB94 D: 2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 16:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRB942	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 16:23:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNWM D: Y9	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.c Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 16:23:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWMY9	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071585**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):** 06-Apr-2021 15:36***** THIS REPEATING FORM HAS BEEN DELETED *****[Back to Form](#)

Date	Location	User	Value	Reason
Mar-11-2021 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Deleted	Changed Information
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

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): 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Form Created	

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

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1. Category:

Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Headache	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-01-2021 11:14:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-01-2021 11:14:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Dec/17/2020 21:00	Changed Information
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Headache: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Dec/17/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO End Date Time: Dec/25/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: RELATED	Initial Entry

Eastern Time (US & Canada)				
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10. Latest Action Taken with Study Treatment:				
Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?				
Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?				
Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:				
Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?				
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Date	Location	User	Value	Reason
Jan-29-2021 08:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-03-2021 09:32:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-02-2021	ACV0PFEINFP6000	Laura Pace	Query 1: Answered	PI assessed as

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071585**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

09:46:06 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)		related as there was not an alternate etiology. Subject denied exposures that could trigger hives.
Feb-01-2021 17:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Please provide rationale for related assessment given temporal relationship to vaccine >10 days. Did patient have any exposures in the interim that could trigger hives?
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: hives; trunk, abdom en, back	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071585

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Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Jan/16/2021 UNK:UN K	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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).

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47	ACV0PFEINFP6000	Laura Pace	Data Entry: NOT APPLICABLE	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

(b) (4)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: RECOVERING/RESO LVING	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-31-2021 19:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071585

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-04-2021 15:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Feb/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-04-2021 15:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-04-2021 15:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Subject Status

Date	Location	User	Value	Reason
Feb-04-2021 15:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Dec-17-2020 16:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Dec-17-2020 16:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-04-2021 15:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/4/2021	Initial Entry
Dec-17-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196b72782\Final\Final On: 06-Apr-2021 19:05 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071585

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

16:37:25 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Dec/17/2020	
Dec-17-2020 16:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Dec/17/2020	Initial Entry

Header Text: c4591001**Visit:** Investigator Signature -
Unscheduled**Form Version:** 22-Apr-2020 21:04**Site No:** 1007**Subject No:** 10071585**Generated By:** (b) (4)**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History**Form Status:** Data Complete, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Casebook Signature**

Date	Location	User	Value	Reason
Mar-11-2021 16:12:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (b) (4)	Data Entry: Click Here to Enable	Initial Entry