

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/11/2021
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11501294]
2.	Birth Date:	(b) (6) /2008
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** DATE OF VISIT

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Jan/11/2021
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Oral Allergy Syndrome]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Vitamin D deficiency]
	Start Date:	UNK/UNK/2020
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Major Depressive Disorder]
	Start Date:	UNK/UNK/2020
	Ongoing:	NO End Date: Jan/1/2021

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Atopic Dermatitis]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** HIV STATUS

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jan/11/2021
2.	Weight:	[129.6]
3.	Unit:	LB
4.	Height:	[63.75]
5.	Unit:	in
6.	Body Mass Index:	[22.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/11/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** RANDOMIZATION

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Jan/11/2021
2.	Randomization Number:	[26564]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
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	[BPTYD1]
5.b	Sample ID	[BPTYD2]
5.c	Sample ID	[BPMDF8]

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**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
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	[BPTYD0]
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** VACCINATION

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/11/2021 14:04
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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Feb/1/2021
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRF9MP]
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/1/2021 17:17
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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Feb/7/2021
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

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

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

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

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
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	[BTZXZS]
5.b	Sample ID	[BTZXZT]
5.c	Sample ID	[BS2D10]

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	May/5/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

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

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	May/5/2021
2.	Date of First Symptom Started:	May/2/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: May/10/2021

**Symptoms**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
<b>Symptoms - Other</b>		
5.a	Symptoms - Other Text:	[Nasal Congestion]

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**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	May/5/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	May/5/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[NALT unknown]

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: May/5/2021
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	[CV18080]
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 30-Apr-2021 01:37

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Health Care Utilization**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 30-Apr-2021 01:37

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

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**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

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

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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Illness Details**

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

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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Illness Details**

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

**Header Text:** c4591001

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

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**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

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

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Imaging**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**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:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**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:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1150    **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294    **Subject Initials:** ---

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

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Lab Urinalysis**

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

**Lab Result**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Vaccination**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

**Site No:** 1150      **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294      **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/3/2021
----	--------------	---

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
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	[BTZXZR]
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form Version:** 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/17/2021

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/17/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/17/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/17/2021
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	[BTZY3M]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/31/2021

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/31/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/31/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/31/2021
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	[BTZY5Z]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/14/2021

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Surveillance Visit**

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

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/14/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Apr/14/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BTZY7B]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Apr/28/2021

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Apr/28/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK8
----	---------------------------------	-------------

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Apr/28/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

**Form Version:** 10-Oct-2020 15:57

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Apr/28/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BTZY8N]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on May/12/2021

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	May/12/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK10
----	---------------------------------	--------------

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on May/12/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

**Form Version:** 10-Oct-2020 15:57

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: May/12/2021
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	[BTFL9F]
-----	-----------	----------

**Header Text:** c4591001

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

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

**Site No:** 1150      **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294      **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

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

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

**Site No:** 1150      **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294      **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left sided mild conductive hearing loss	Jan/14/2021 UNK:UNK	NO End Date Time:  May/UNK/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Pain at injection site	May/27/2021 18:00	NO End Date Time:  May/29/2021 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Swollen at injection site	May/27/2021 18:00	NO End Date Time:  May/29/2021 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Pain at injection site	Jun/16/2021 18:00	NO End Date Time:  Jun/17/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left sided mild conductive hearing loss]
4.	Start Date Time:	Jan/14/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: May/UNK/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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:** 1150

**Subject No:** 11501294

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain at injection site]
4.	Start Date Time:	May/27/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: May/29/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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:** 1150

**Subject No:** 11501294

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Swollen at injection site]
4.	Start Date Time:	May/27/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: May/29/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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:** 1150

**Subject No:** 11501294

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain at injection site]
4.	Start Date Time:	Jun/16/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jun/17/2021 UNK:UNK
6.	Toxicity Grade:	1

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Form:** MEDICATION ERROR

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Medication Error**

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

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**Radiation Treatment**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	May/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Withdrawal Of Consent**

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



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1. Consent Was:

OBTAINED

Date Written Consent Obtained

May/27/2021

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	May/27/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 30-Apr-2021 01:41

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	May/27/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: May/27/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BTFLJS]
5.b	Sample ID	[BTFLJT]
5.c	Sample ID	[BVCKYS]

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: May/27/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V101\_VAX3

**Form:** VACCINATION

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	May/27/2021 14:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** DATE OF VISIT

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jun/16/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 30-Apr-2021 01:41

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jun/16/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jun/16/2021
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	[BTFLMW]
-----	-----------	----------

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jun/16/2021 16:11
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form:** DATE OF VISIT

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jul/15/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** CONTACT OUTCOME

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jul/15/2021
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1150

**Subject No:** 11501294

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Jul/15/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Mar/3/2021

**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:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Jan-11-2021 14:39:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	May-27-2021 15:22:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-17-2021 16:47:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Shelly Senders	Approved	Mar-10-2021 23:37:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
----------------	----------	--	------	--------

**Affidavit:**

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

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

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

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Jan-11-2021 14:38:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 14:38:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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*1. Consent Was:*

Date	Location	User	Value	Reason
Jan-11-2021 14:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/11/2021	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1150

**Subject No:** 11501294

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

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

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Jan-11-2021 14:38:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 11501294	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Jan-11-2021 14:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2008	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Jan-11-2021 14:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Jan-11-2021 14:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRICAN AM ERICAN	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

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

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-11-2021 14:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-11-2021 14:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-11-2021 14:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1150**Site Name:** (1150) Senders Pediatrics**Subject No:** 11501294**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Jan-11-2021 14:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 1 <b>mber:</b> <b>Medical Histo</b> Oral Allergy <b>ry Term:</b> Syndrome <b>Start Date:</b> UNK/UNK/2 010 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 14:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 14:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Oral Allergy Syndrome	Initial Entry

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

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-11-2021 14:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Jan-11-2021 14:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Jan-11-2021 14:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 2 <b>mber:</b> <b>Medical Histo</b> Vitamin D de <b>ry Term:</b> ficiency <b>Start Date:</b> UNK/UNK/2 020 <b>Ongoing:</b> YES	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 14:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Vitamin D deficiency	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Jan-11-2021 14:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Jan-11-2021 14:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:42:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N umber:</b> 3 <b>Medical History Term:</b> Major Depressive Disorder <b>Start Date:</b> UNK/UNK/2020 <b>Ongoing:</b> NO End Date: Jan/1/2021	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:42:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

***1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Jan-11-2021 14:42:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Major Depressive Disorder	Initial Entry

***1.c Start Date:***

Date	Location	User	Value	Reason
Jan-11-2021 14:42:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

***1.c Ongoing:***

Date	Location	User	Value	Reason
Jan-11-2021 14:42:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jan/1/2021	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

*1.d*

Date	Location	User	Value	Reason
Jan-11-2021 14:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Atopic Dermatitis <b>Start Date:</b> UNK/UNK/ 2015 <b>Ongoing:</b> YES	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

***1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Jan-11-2021 14:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Atopic Dermatitis	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Jan-11-2021 14:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Jan-11-2021 14:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.e***

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>Medical History Term:</b> Asthma <b>Start Date:</b> UNK/UNK /2015 <b>Ongoing:</b> YES	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

***1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Jan-11-2021 14:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Asthma	Initial Entry

***1.e Start Date:***

Date	Location	User	Value	Reason
Jan-11-2021 14:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.e Ongoing:***

Date	Location	User	Value	Reason
Jan-11-2021 14:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

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

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known t o be HIV POSITIVE	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**1. Date:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 129.6	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> 63.75	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		
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**5. Unit:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 22.4	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature: 98.5</b> <b>Temperature U F</b> <b>nit:</b> <b>Temperature L ORAL CA</b> <b>ocation:: VITY</b>	Initial Entry

**7.a Record Identifier:**

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 98.5	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-11-2021 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def</b> 113 <b>ined Identifi</b> <b>er:</b> <b>Test::</b> Choriogonadot ropin Beta_PX 113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-11-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

14:45:54 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Choriogonadotropin Beta_P X113
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**6.a Result:**

Date	Location	User	Value	Reason
Jan-11-2021 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

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

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 26564	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 14:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

Jan-11-2021 14:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/11/2021	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPTYD1	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BPTYD1	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPTYD2	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BPTYD2	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPMDF8	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 14:46:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BPMDF8	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 14:47:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

Jan-11-2021 14:47:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/11/2021	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPTYD0	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BPTYD0	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1150

**Subject No:** 11501294

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

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

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021 14:04	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

Jan-11-2021 14:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Jan-11-2021 14:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED F OR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1150

**Subject No:** 11501294

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

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

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

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-01-2021 17:52:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Feb/1/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?</b> :	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or system ic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or systemi</b> N <b>c symptoms present o</b> O <b>n the last day the Subj</b> <b>ect Diary was complet</b> <b>ed?:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G <b>Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED MUSCL E PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD MU SCLE 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-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERD JOINT PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

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

**2.h Symptom:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOI NT 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-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/1/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature: 98.9</b> <b>Temperature U F</b> <b>nit:</b> <b>Temperature L ORAL CA</b> <b>ocation:: VITY</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Feb-01-2021 17:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 98.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/1/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34	ACV0PF EINFP60	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
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**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX 113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**6.a Test:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_P X113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-01-2021 17:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-01-2021 17:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 17:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Feb-01-2021 17:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/1/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-01-2021 17:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRF9MP	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-01-2021 17:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRF9MP	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-01-2021 17:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-01-2021 17:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-01-2021 17:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-01-2021 17:54:31 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/1/2021 17:17	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-01-2021 17:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-01-2021 17:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-01-2021 17:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-01-2021 17:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-01-2021 17:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> YES	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-03-2021 17:09:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Mar/3/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?</b> :	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FATIGU E <b>Were fever or sys</b> YES <b>temic symptoms</b> Ongo <b>present on the la</b> g? <b>st day the Subjec</b> <b>t Diary was com</b> NO <b>pleted?:</b>  Stop Dat e:  Fe b/ 7/ 20 21	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Feb/7/2021	Initial Entry

2.c

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.e Symptom:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.f Symptom:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	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
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED MUSCLE PAIN	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERED JOINT	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			PAIN	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.h Symptom:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE DN ES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTI ON SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Mar-03-2021 17:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-03-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-03-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-03-2021 17:10:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150 Site Name: (1150) Senders Pediatrics

Subject No: 11501294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Mar-03-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 17:10:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BTZXZS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 17:10:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZXZS	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 17:11:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BTZXZT	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZXZT	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BS2D10	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BS2D10	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jun-22-2021 02:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jun-21-2021 14:23:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Answered	convalescent visit not being performed due to amendment
Jun-18-2021 07:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Opened	PDQ : Please confirm whether corresponding convalescent visit has been performed OR not. If yes, enter the details of same. Else, confirm CONVA has not been performed yet as.
May-06-2021 10:29:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
May-06-2021 10:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
May-06-2021 10:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
May-06-2021 10:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/5/2021	Initial Entry

**3. COVID-19 Illness Visit:**

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
May-06-2021 10:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form Version:** 30-Apr-2021 01:47

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/5/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/2/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jun-07-2021 08:54:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-03-2021 15:05:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
Jun-03-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	New

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

15:05:59 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	NO Date of Last Symptom Re solved:  May/10/2021	Information
May-30-2021 14:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Clin: As subject was recently vaccinated on 27May2021, please clarify whether the reported symptoms are still ongoing. If symptoms have ended, please update 'Symptoms Ongoing' to 'NO' and add Date of Last Symptom Resolved on the CRF.
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVE R <b>Symptom Present</b> NO :	Initial Entry
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**4.a Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCR <b>s:</b> EASED COUG H <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**4.b Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED CO UGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR INCRE <b>oms:</b> ASED SHORTNE SS OF BREATH  <b>Sympt</b> NO <b>om Pre</b> <b>sent:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**4.c Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILL S <b>Symptom Present</b> NO :	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**4.d Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**4.e Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED M USCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW LOSS OF TASTE OR SME LL <b>Symptom Present:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**4.f Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCRE ASED SORE TH ROAT <b>Symptom Present:</b> YES	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**4.g Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SO RE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRH EA <b>Symptom Pres ent:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**4.h Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:47

**Form Status:** Data Complete, Not Complete

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**4.i Symptoms:**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
May-06-2021 10:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-06-2021 10:28:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms -</b> Nasal Cong <b>Other:</b> estion	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
May-06-2021 10:28:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Nasal Congestion	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/5/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYN DROME CORONAVIRUS 2	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Time (US & Canada)

**5. Device Type:**

Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
May-06-2021 10:29:05 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NALT unknown	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Time (US & Canada)				
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-06-2021 10:29:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-06-2021 10:29:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-06-2021 10:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-06-2021 10:29:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
May-06-2021 10:29:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  May/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-06-2021 10:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> CV18080	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-06-2021 10:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> CV18080	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-06-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-06-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-06-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
May-06-2021	ACV0PF	auto query	Query 1: Closed	Close Auto

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**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:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

16:46:08 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(autoquery)		Query
May-06-2021 16:46:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> self swab only	New Information
May-06-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
May-06-2021 10:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> self swab only	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1.a*

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

Date	Location	User	Value	Reason
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGE NCY ROO M <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHY SICIAN	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

			<b>Occurrence NO of Visits or C ontacts:</b>	
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***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICI AN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitio</b> URGEN <b>ner:</b> T CARE <b>Occurrence of V</b> NO <b>isits or Contacts:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> TELEPHON <b>titioner:</b> E CONSULT ATION  <b>Occurrence</b> NO <b>of Visits or C</b> <b>ontacts:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTA TION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner</b> OTH : ER <b>Occurrence of Visits</b> NO <b>or Contacts:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
May-06-2021 10:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on May/05/2021

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
May-06-2021 10:30:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILL NESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
May-06-2021 10:30:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
May-06-2021 10:30:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-03-2021 17:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Mar/3/2021	Initial Entry



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Consent Was:**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Mar/3/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Mar-03-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

17:11:59 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	combined with visit 3 draw	
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**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
Unscheduled SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-03-2021 17:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-03-2021 17:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-03-2021 17:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 17:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Mar-03-2021 17:12:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/3/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-03-2021 17:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTZXZR</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 17:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZXZR	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/3/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/17/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-17-2021 16:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/17/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Mar-17-2021 16:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK2	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/17/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-17-2021 16:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-17-2021 16:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-17-2021 16:48:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-17-2021 16:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/17/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Mar-17-2021 16:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/17/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-17-2021 16:48:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTZY3M</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-17-2021 16:48:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZY3M	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/31/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-31-2021 14:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/31/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Mar-31-2021 14:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK4	Initial Entry

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/31/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-31-2021 14:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-31-2021 14:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-31-2021 14:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-31-2021 14:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/31/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Mar-31-2021 14:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/31/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-31-2021 14:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTZY5Z</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-31-2021 14:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZY5Z	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/14/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Apr-14-2021 17:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/14/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-14-2021 17:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK6	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/14/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-14-2021 17:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-14-2021 17:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-14-2021 17:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-14-2021 17:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Apr/14/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Apr-14-2021 17:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/14/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-14-2021 17:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BTZY7B</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-14-2021 17:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZY7B	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Apr/28/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Apr-28-2021 17:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/28/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-28-2021 17:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK8	Initial Entry



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Apr/28/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-28-2021 17:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-28-2021 17:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-28-2021 17:39:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-28-2021 17:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Apr/28/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
Apr-28-2021 17:39:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-28-2021 17:39:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BTZY8N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-28-2021 17:39:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTZY8N	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on May/12/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
May-13-2021 17:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/12/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
May-13-2021 17:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK10	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on May/12/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-13-2021 17:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-13-2021 17:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-13-2021 17:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-13-2021 17:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on May/12/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
May-13-2021 17:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  May/12/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-13-2021 17:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BTFL9F	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-13-2021 17:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTFL9F	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150      **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
May-27-2021 15:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> May/13/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

**Site No:** 1150 **Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
May-27-2021 15:22:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-27-2021 15:21:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
May-27-2021 15:21:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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**1. Category:**

Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jun-01-2021 13:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Jun-01-2021 12:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 5: Answered	LAR is legally authorized representative - the mother. Determination of

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				resolution was per subject and mom.
Jun-01-2021 10:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 5: Reissued:Opened	clinical : Thanks but please clarify what "LAR" refers to and confirm determination of resolution was by subject self report or if audiometry done.
Jun-01-2021 10:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 5: Answered	Per mother hearing has resolved no scans completed
May-27-2021 16:49:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 5: Reissued:Opened	clin: Thanks but please clarify what "LAR" refers to and if resolution is based on subject self report if audiometry done. Please also provide results of CT scan if done.
May-27-2021 15:21:24	ACV0PF EINFP60	(b) (4), (b) (6)	Query 5: Answered	Per LAR hearing loss has resolved

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(UTC-05:00) Eastern Time (US & Canada)	00			
May-27-2021 11:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 5: Opened	clinical: please provide information regarding CT scan and ENT follow up from visit scheduled for May 18th. Thanks.
May-12-2021 11:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
May-10-2021 14:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
May-04-2021 14:30:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Answered	Original value is correct
May-03-2021 16:43:23 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	no other viral symptoms were present at the time

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Canada)				
May-03-2021 13:51:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Reissued:Open d	GPD Clin: please respond to query with findings on otoscope exam, else confirm that otoscopic exam was not performed.
May-03-2021 13:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Open d	GPD Clin: please confirm if patient did or did not have any associated viral symptoms such as sinus/nasal congestion, inflamed tympanic membranes, etc.
Apr-21-2021 09:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Answered	Original value is correct
Apr-21-2021 09:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	Original value is correct

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Apr-19-2021 09:53:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Opened	GPD Clin: please respond to query with presence or absence of associated symptoms.
Apr-19-2021 09:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Reissued:Opened	GPD Clin: please respond to query with confirmation of presence or absence of findings on otoscopic exam. If otoscopic exam was not performed, please indicate this in response.
Apr-19-2021 08:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Answered	Original value is correct
Apr-19-2021 08:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Apr-14-2021 15:18:38 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Reissued:Opened	GPD Clin:Did patient have any of the following

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Eastern Time (US & Canada)				associated symptoms: URI symptoms, sinus or nasal congestion, rhinorrhea at the onset of conductive hearing loss.
Apr-14-2021 12:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	GPD Clin: Thank you for clarification. Did participant have any of the following otoscopic findings associated with event: middle ear effusion, tympanosclerosis, perforated tympanic membrane (TM), otosclerosis, or other TM/canal/middle ear abnormality?
Apr-14-2021 09:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information

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Apr-14-2021 09:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Changed Information
Apr-14-2021 09:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Left sided mild conductive hearing loss	Changed Information
Apr-13-2021 21:28:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Opened	GPD Clin:please provide specific type of Hearing loss as assessed by evaluating ENT or other physician. For example, subjective hearing loss with middle ear effusion on otoscopic exam, or sensorineural loss by formal audiometry testing.
Apr-13-2021 21:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Closed	reissuing revised query

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Apr-12-2021 17:31:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Opened	GPD Clin: please provide specific type of Hearing loss as assessed by investigator or evaluating physician. For example, middle ear effusion on otoscopic exam, or sensorineural loss by formal testing.
Apr-12-2021 17:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	issuing revised query
Apr-12-2021 17:09:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	GPD Clin: Did patient have any associated symptoms at the time of onset which may have warranted evaluation and COVID testing?
Apr-12-2021 17:05:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please provide specific type of Hearing loss as provided by specialist that

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				evaluated patient's hearing loss.
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Hearing Loss Left Ear	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
May-11-2021 14:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
May-11-2021 13:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Changed Information
May-11-2021 13:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021 UNK:UNK	Changed Information
May-05-2021 10:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	clinical: have received information from CRA that

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Canada)				start date of symptoms was Jan 14th. Please review again and update CRF with actual start date if this information is correct. Thanks.
Apr-14-2021 15:18:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Apr-14-2021 09:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	per subject yes this occurred after first vaccination
Apr-12-2021 17:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm that Hearing loss occurred after first vaccination and number of days following first vaccination.
Apr-12-2021 08:42:03 (UTC-05:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/UNK/2021 UNK:UNK	Initial Entry

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Eastern Time (US & Canada)

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
May-27-2021 15:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  May/UNK/2021 UNK: UNK	New Information
Apr-14-2021 15:19:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Apr-14-2021 09:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	there is no spot to enter this in the diary, and subject did not mention this occurring until this month
Apr-12-2021 17:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: AE of hearing loss was not reported on symptom diary at the time of VAX2. Please confirm that AE is still ongoing

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				since Jan 2021.
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

**If Yes, record the type of medication error on the Medication Error Log.**

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Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
May-12-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query

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**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
May-03-2021 16:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	no follow up has occurred yet
May-03-2021 13:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD Clin: please provide any follow up assessment by ENT and results of initial and follow up hearing exam
Apr-21-2021 09:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Apr-19-2021 09:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD Clin: please provide PI rationale for assessing conductive hearing loss as related to study intervention.

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Apr-19-2021 08:45:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	per PI assessment
Apr-14-2021 15:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Open ed	GPD Clin: please provide rationale for unilateral conductive hearing loss being related to study intervention.
Apr-14-2021 09:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	subject does not have anything related in medical history
Apr-12-2021 17:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm if patient does/does not have medical history of recurrent ear infections or other risk factors for decreased hearing acuity.

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Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Apr-14-2021 15:19:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Apr-14-2021 09:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	subject will follow up with ENT in one month to retest hearing
Apr-12-2021 17:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: please confirm treatment and follow up that were provided for the AE Hearing loss
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
May-27-2021 15:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
May-27-2021 15:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

May-27-2021 15:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	For AE Left sided mild conductive hearing loss: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Apr-12-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Pain at injection site	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/27/2021 18:00	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)				
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  May/29/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)				
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**8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jun-16-2021 16:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Category:**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Swollen at injection site	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/27/2021 18:00	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  May/29/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)				
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**8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jun-16-2021 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Category:**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Pain at injection site	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/16/2021 18:00	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jun/17/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)				
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**8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4), (b) (6)		
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jul-15-2021 09:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
May-27-2021 15:22:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/13/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
May-27-2021 15:22:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
May-27-2021 15:22:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> May/27/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER  
VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Consent Was:**

Date	Location	User	Value	Reason
May-27-2021 15:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  May/27/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
May-27-2021 15:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/27/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
May-27-2021 15:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
May-27-2021 15:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
May-27-2021 15:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
May-27-2021 15:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
May-27-2021 15:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/27/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
May-27-2021 15:23:01	ACV0PF EINFP60	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
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5. Specimen Type:

Date	Location	User	Value	Reason
May-27-2021 15:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
May-27-2021 15:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def ined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX 113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
May-27-2021 15:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**6.a Test:**

Date	Location	User	Value	Reason
May-27-2021 15:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_P X113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
May-27-2021 15:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-27-2021 15:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-27-2021 15:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-27-2021 15:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-27-2021 15:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
May-27-2021 15:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  May/27/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-27-2021 15:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BTFLJS	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-27-2021 15:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTFLJS	Initial Entry

**5.b**

Date	Location	User	Value	Reason
May-27-2021 15:23:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BTFLJT	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
May-27-2021 15:23:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTFLJT	Initial Entry

**5.c**

Date	Location	User	Value	Reason
May-27-2021 15:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BVCKYS	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
May-27-2021 15:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BVCKYS	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-27-2021 15:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-27-2021 15:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-27-2021 15:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-27-2021 15:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
May-27-2021 15:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  May/27/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-27-2021 15:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BTFLJR	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-27-2021 15:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTFLJR	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/27/2021 14:00	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**9. Unit:**

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
May-27-2021 15:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jun-16-2021 16:46:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Jun/16/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/16/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Specimen Type:

Date	Location	User	Value	Reason
Jun-16-2021 16:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jun-16-2021 16:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def</b> 113 <b>ined Identifi</b> <b>er:</b> <b>Test::</b> Choriogonadot ropin Beta_PX 113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jun-16-2021 16:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jun-16-2021	ACV0PF	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

16:47:06 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Choriogonadotropin Beta_P X113
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**6.a Result:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-16-2021 16:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Jun-16-2021 16:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jun/16/2021	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BTFLMW	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTFLMW	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/16/2021 16:11	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
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090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Jun-16-2021 16:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jul-15-2021 09:58:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Jul/15/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Contact Type:**

Date	Location	User	Value	Reason
Jul-15-2021 09:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Jul-15-2021 09:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Jul/15/2021	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit  
Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jul-15-2021 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/15/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jul-15-2021 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jul-15-2021 09:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1150

**Site Name:** (1150) Senders Pediatrics

**Subject No:** 11501294

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Subject Status**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Jan-11-2021 14:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Jan-11-2021 14:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-03-2021 17:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Mar/3/2021	Initial Entry
Jan-11-2021 14:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Jan/11/2021	Initial Entry
Jan-11-2021 14:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

090177e198913803\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1150

**Subject No:** 11501294

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1150) Senders Pediatrics

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Jan-28-2021 11:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry