

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/19/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11501022]
2.	Birth Date:	(b) (6) 1988
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

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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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/19/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Type 2 Diabetes]
	Start Date:	Jul/31/2019
	Ongoing:	YES

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/19/2020
2.	Weight:	[345.0]
3.	Unit:	LB
4.	Height:	[73.0]
5.	Unit:	in
6.	Body Mass Index:	[45.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.9]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/19/2020
2.	Randomization Number:	[57299]
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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6CST]
5.b	Sample ID	[BN6CSV]
5.c	Sample ID	[BN6CSW]
5.d	Sample ID	[BL9RHX]
5.e	Sample ID	[BL9RHY]

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6CSS]
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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:	Aug/19/2020 17:29
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	---

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/8/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6D2P]
-----	-----------	----------

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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:	Sep/8/2020 12:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/12/2020
2.	Erroneous Visit	

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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6D81]
5.b	Sample ID	[BL9RSX]

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: 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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

Unplanned Assessments

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

Header Text: c4591001

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

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Disposition - Follow-Up

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

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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

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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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Kidney Stones	Dec/2/2020 UNK:UNK	NO End Date Time: Dec/8/2020 UNK: UNK	Repeating Pages
2.	ADVERSE EVENT	2	Pain at injection site	Jan/19/2021 18:00	NO End Date Time: Jan/20/2021 UNK: UNK	Repeating Pages
3.	ADVERSE EVENT	3	Fatigue	Jan/19/2021 18:00	NO End Date Time: Jan/20/2021 UNK: UNK	Repeating Pages
4.	ADVERSE EVENT	4	Muscle Pain	Jan/19/2021 18:00	NO End Date Time: Jan/20/2021 UNK: UNK	Repeating Pages
5.	ADVERSE EVENT	5	Pain at injection site	Feb/9/2021 UNK:UNK	NO End Date Time: Feb/10/2021 UNK: UNK	Repeating Pages

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
6.	ADVERSE EVENT	6	Headache	Feb/9/2021 UNK:UNK	NO End Date Time: Feb/12/2021 UNK: UNK	Repeating Pages
7.	ADVERSE EVENT	7	Fatigue	Feb/9/2021 UNK:UNK	NO End Date Time: Feb/12/2021 UNK: UNK	Repeating Pages

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Kidney Stones]
4.	Start Date Time:	Dec/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/8/2020 UNK:UNK
6.	Toxicity Grade:	3

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021051527]

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1150

Subject No: 11501022

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain at injection site]
4.	Start Date Time:	Jan/19/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/20/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Jan/19/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/20/2021 UNK:UNK
6.	Toxicity Grade:	2

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle Pain]
4.	Start Date Time:	Jan/19/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/20/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain at injection site]
4.	Start Date Time:	Feb/9/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/10/2021 UNK:UNK
6.	Toxicity Grade:	2

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Feb/9/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/12/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Feb/9/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/12/2021 UNK:UNK
6.	Toxicity Grade:	2

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Medication Error

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Radiation Treatment

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

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

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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?	

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Contact Outcome

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

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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/18/2021
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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[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: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/18/2021
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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/19/2021
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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/19/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/19/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/19/2021
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	[BRF9J3]
5.b	Sample ID	[BPMDGR]
5.c	Sample ID	[BPMDGS]

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/19/2021
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	[BRF9J4]
-----	-----------	----------

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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:	Jan/19/2021 13:51
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
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	[BRF9T0]
-----	-----------	----------

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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:	Feb/8/2021 13:41
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/8/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/8/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/12/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Shelly Senders	Approved	Mar-09-2021 20:16:41 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-19-2020 19:53:13 (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: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-19-2021 17:46:00 (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, Signed, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Shelly Senders	Approved	Mar-09-2021 20:16:41 (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.

(b) (6)	N/A	Feb-08-2021 14:09:48 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

Shelly Senders	Approved	Jan-23-2021 20:19:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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.

(b) (6)	N/A	Jan-19-2021 17:44:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Shelly Senders	Approved	Oct-28-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-19-2020 19:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 19:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHOR TS	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-19-2020 19:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-19-2020 19:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-19-2020 19:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11501022	Transcription Error
Aug-19-2020 19:52:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Subject ID is expected to be in 8 digits. Please review.
Aug-19-2020 19:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1151022	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:50:43	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1988	Enrollment Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

3. Sex:

Date	Location	User	Value	Reason
Aug-19-2020 19:52:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-19-2020 19:52:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 19:52:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 19:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - 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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-19-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-19-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-19-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-19-2020 19:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 1 Medical History Term: Type 2 Diabetes Start Date: Jul/31/2019 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 19:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type 2 Diabetes	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

1.a Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/31/2019	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-24-2020 06:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site's confirmation.
Aug-21-2020 08:01:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Weight is not clinically significant. Deemed healthy per physical.
Aug-21-2020 06:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM1: Confirmation on the out of range value as clinically significant or

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

				not is expected. Please review and confirm.
Aug-20-2020 09:49:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-20-2020 03:56:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Please verify the weight and unit reported as 345 lb is outside the normal range 25-136 for kg or 50-300 for lb. If correct kindly confirm if it is clinically significant. If yes please report corresponding event on medical history page. Else clarify.
Aug-19-2020 19:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 345 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 345.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 73.0	Initial Entry

5. Unit:

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 45.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.9 Temperature Unit: Temperature Location: HEAD	Initial Entry

7.a Record Identifier:

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

& Canada)				
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-19-2020 19:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 57299	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 19:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 19:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-19-2020 19:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 19:55:25 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 19:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 19:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BN6CS D: T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6CST	Initial Entry

5.b

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Aug-19-2020 19:55:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BN6CS D: V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:55:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6CSV	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-19-2020 19:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BN6CS D: W	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6CSW	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-19-2020 19:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BL9RH D: X	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9RHX	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-19-2020 19:57:01	ACV0PFEINFP6000	(b) (6)	Data Entry: Sample I BL9RH	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	D:	Y	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9RHY	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 19:58:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 19:58:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-19-2020 19:58:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 19:58:32 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 19:58:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 19:58:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BN6CS D: S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:58:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6CSS	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020 17:29	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 20:00:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-19-2020 20:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-09-2020 09:00:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-09-2020 09:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 09:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location:: 1 98.2 F CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 09:01:40 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 09:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 09:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-09-2020 09:01:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-09-2020 09:01:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-09-2020 09:01:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-09-2020 09:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 09:01:55 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 09:01:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 09:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6D2P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 09:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6D2P	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020 12:09	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 09:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 12:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/12/2020	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 12:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 12:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 12:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 12:06:45 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 12:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 12:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BN6D8 : 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 12:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6D81	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

Oct-13-2020 12:07:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BL9RS : X	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 12:07:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BL9RSX	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

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

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-13-2020 12:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-13-2020 12:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 12:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (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 - 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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Kidney Stones	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020 UNK:U NK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/8/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-21-2021 04:11:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Kidney Stones: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death?	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			<p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>
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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
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify</i> : unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 15:06:00 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

& Canada)

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-21-2021 04:11:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021051527	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pain at injection site	Initial Entry

4. Start Date Time:

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/20/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Feb-08-2021 14:12:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/20/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Feb-08-2021 14:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle Pain	Initial Entry

4. Start Date Time:

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/20/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Feb-08-2021 14:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pain at injection site	Initial Entry

4. Start Date Time:

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/10/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Mar-08-2021 10:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

4. Start Date Time:

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/12/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Mar-08-2021 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/12/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Mar-08-2021 10:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 17:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/18/2021	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: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-19-2021 17:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 17:45:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-19-2021 17:45:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is will ing to return for V accination 3 Participant is: eligible per loc al/national rec ommendations and confirmed	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

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

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

Subject No: 11501022 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:56

			to have receive d only placebo at Vaccination 1/2	
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - 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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-19-2021 17:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/18/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-19-2021 17:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBIL ITY FOR ADDITI ONAL VACCINAT ION	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 17:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-19-2021 17:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/19/2021	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-19-2021 17:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-19-2021 17:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-19-2021 17:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 17:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 17:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-21-2021 03:32:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 08:30:34 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)				
Jan-20-2021 07:26:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 17:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 17:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 08:31:22 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRF9J D: 3	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

& Canada)

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 08:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRF9J3	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 08:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPMD D: GR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 08:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPMDGR	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Jan-20-2021 08:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPMD D: GS	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 08:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPMDGS	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 17:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 17:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-21-2021 00:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Jan-20-2021 08:30:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Changed data per query

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)				
Jan-20-2021 07:26:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 17:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 17:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 08:31:59 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRF9J D: 4	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

& Canada)				
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5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 08:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRF9J4	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021 13:51	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 17:47:56	ACV0PFEINFP6000	(b) (6) [Redacted]	Data Entry: YES	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)		
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Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 14:09:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Feb/8/2021	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-08-2021 14:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 14:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-08-2021 14:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 14:09:57 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 14:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-08-2021 14:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRF9T : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 14:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRF9T0	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021 13:41	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 14:11:12	ACV0PFEINFP6000	(b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

(b) (4)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1150

Subject No: 11501022

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): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 10:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Mar/8/2021	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Mar-08-2021 10:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-08-2021 10:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/8/2021	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (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: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-08-2021 10:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-08-2021 10:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREAT MENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-08-2021 10:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-13-2020 12:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-19-2020 19:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-13-2020 12:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/12/2020	Initial Entry
Aug-19-2020 19:55:07	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1150

Site Name: (1150) Senders Pediatrics

Subject No: 11501022

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-05:00) Eastern Time (US & Canada)				
Aug-19-2020 19:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1150

Subject No: 11501022

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1150) Senders Pediatrics

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 00:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Shelly Senders (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2f8b\Final\Final On: 01-Apr-2021 03:46 (GMT)