

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[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

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/6/2020
----	--------------	---

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12321299]
2.	Birth Date:	(b) (6) 1965
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/6/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

**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
----	--	----------------

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**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Oct/6/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Answered Queries, Verified

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[Form Comments](#)

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Undiagnosed Hypertension]
	Start Date:	Oct/6/2020
	Ongoing:	YES

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**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 15-Sep-2020 21:56**Site No:** 1232**Subject No:** 12321299**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1232) Columbus Regional Research Institute**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:24[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Oct/6/2020
2.	Weight:	[180.0]
3.	Unit:	LB
4.	Height:	[73.0]
5.	Unit:	in
6.	Body Mass Index:	[23.7]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[37.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY



**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** RANDOMIZATION

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/6/2020
2.	Randomization Number:	[103758]
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:** 1232**Site Name:** (1232) Columbus Regional Research Institute**Subject No:** 12321299**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
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	[BR8K9X]
5.b	Sample ID	[BR8K9Y]
5.c	Sample ID	[BR8K9Z]
5.d	Sample ID	[BNTLDK]
5.e	Sample ID	[BNTLDL]

**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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
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	[BR8K9C]
-----	-----------	----------

**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[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:	Oct/6/2020 10:13
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Verified

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ [ ]	<a href="#">Comments</a>
	Unit:	Not Done _____	<a href="#">Comments</a>
	Temperature Location:	Not Done _____	<a href="#">Comments</a>

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	Not Done _____	<a href="#">Comments</a>
2.	Sample Type	Not Done _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Done _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Done _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ [ ]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	Not Done _____	<a href="#">Comments</a>
2.	Treatment Name	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Done _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Done _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Done _____	<a href="#">Comments</a>
6.	Body Side:	Not Done _____	<a href="#">Comments</a>
7.	Route:	Not Done _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Done _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Done _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Done _____	<a href="#">Comments</a>

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done	<a href="#">Comments</a>
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**Header Text:** C4591001

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

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

**Site No:** 1232 **Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Date of Visit**

1.	Date of Visit	//
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:** Not Started**Site No:** 1232**Site Name:** (1232) Columbus Regional Research Institute**Subject No:** 12321299**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001**Visit:** V4\_MONTH6\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1232**Site Name:** (1232) Columbus Regional Research Institute**Subject No:** 12321299**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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:** 1232**Subject No:** 12321299**Generated By:**

(b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19**Form Status:** Not Started**Site Name:** (1232) Columbus Regional Research Institute**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:24**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:	[ ]
----	------------------------	-----

**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

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

**Form Status:** Not Started

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

**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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090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232**Site Name:** (1232) Columbus Regional Research Institute**Subject No:** 12321299**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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?	
----	--	--

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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:** 1232**Site Name:** (1232) Columbus Regional Research Institute**Subject No:** 12321299**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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:** 1232**Site Name:** (1232) Columbus Regional Research Institute**Subject No:** 12321299**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

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

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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:** 1232    **Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299    **Subject Initials:** ---

**Generated By:**    **Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Unplanned Assessments**

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Not Started

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

**Adverse Event Report**

1.	Category:	
2.	AE ID:	[ ]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Not Started

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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>	
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>	
9.	<p>Is this event related to study treatment:</p>	
10.	<p>Latest Action Taken with Study Treatment:</p>	
11.	<p>Was a Concomitant Medication given?</p>	

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[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	[ ]

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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**Concomitant Medications**

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

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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**Concomitant Medications**

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

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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**Radiation Treatment**

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

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

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

**Header Text:** C4591001

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

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Queries, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/6/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	OTHER
4.	Specify Status:	[Subject did not receive V2 vaccination due to investigator decision and was then lost to follow up]

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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?	

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Contact Outcome**

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

**Header Text:** C4591001

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

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

**Site No:** 1232 **Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
----	--------------	--

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1232**Site Name:** (1232) Columbus Regional Research Institute**Subject No:** 12321299**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Disposition - Follow-Up**

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

**Header Text:** C4591001

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

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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

**Header Text:** C4591001

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

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Further Vaccination Confirmation**

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



**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Treatment Unblinded**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**Withdrawal Of Consent**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

**Death Details**

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

**Cause of Death**

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

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Oct/6/2020

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA -  
Comments

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

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
Form	Oct-06-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY - Comments

**Form Status:** Data Complete, Answered Queries, Verified

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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Item	Date	User	Comment
Form	Mar-12-2021 14:52:03 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Oct-06-2020 10:02:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
Form	Jan-27-2021 13:48:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
1	Jan-27-2021 13:48:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2	Jan-27-2021 13:48:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
1	Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
2.a	Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
Form	Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
1	Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2	Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
3	Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
4	Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
Form	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
1	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
2	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
3	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
4	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
5	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
6	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
7	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
8	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
9	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
10	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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Item	Date	User	Comment
11	Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-27-2021 13:48:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

(b) (6)	Approved	Nov-10-2020 14:02:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------	----------	--	------	--------

**Affidavit:**

By my dated signature below, I, (b) (6) 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.

Jeffrey Kingsley	Approved	Nov-10-2020 14:02:51 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Status:** Data Complete, Verified

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

**Affidavit:**

By my dated signature below, I, JeffreyKingsley, 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.

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-06-2020 10:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 10:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHOR TS	Initial Entry

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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*1. Consent Was:*

Date	Location	User	Value	Reason
Oct-06-2020 10:01:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Con sent Obtained  Oct/6/2020	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Oct-06-2020 10:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12321299	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-06-2020 10:01:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1965	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-06-2020 10:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Oct-06-2020 10:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Oct-06-2020 10:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRI CAN AMERICAN	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

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

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-09-2020 06:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 09:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Oct-08-2020 01:53:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update details on SWAB TRK, and SWAB PFE forms or else clarify. Thank you.
Oct-06-2020 10:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Oct-06-2020 10:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-06-2020 10:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-06-2020 10:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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, Answered Queries, Verified**Site No:** 1232**Site Name:** (1232) Columbus Regional Research Institute**Subject No:** 12321299**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Mar-12-2021 14:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical</b> Undiagnos <b>History T</b> ed Hyperte <b>erm:</b> nsion <b>Start Dat</b> Oct/6/2020 <b>e:</b> <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Mar-12-2021 14:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 14:53:18 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Undiagnosed Hypert ension	Initial Entry

**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, Answered Queries, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-12-2021 14:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Illness was first noticed at V1. Patient was instructed to see PCP.
Mar-12-2021 14:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 06/Oct /2020. Please review and update as appropriate.
Mar-12-2021 14:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Mar-12-2021 14:53:18	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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, Answered Queries, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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

(b) (4), (b) (6)

**Header Text:** C4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 180.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 73.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23.7	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Id 1	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Eastern Time (US & Canada)			<b>entifier::</b> <b>Temperat 37.4</b> <b>ure:</b> <b>Temperat C</b> <b>ure Unit:</b> <b>Temperat ORAL</b> <b>ure Locat CAVI</b> <b>ion:: TY</b>
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.4	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
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090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry
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**7.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-06-2020 10:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-06-2020 10:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 103758	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-08-2020 09:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-08-2020 09:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-08-2020 09:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/6/2020	Initial Entry

**5.a**

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Date	Location	User	Value	Reason
Oct-08-2020 09:35:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BR8K9</b> <b>D: X</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 09:35:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8K9X	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-08-2020 09:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BR8K9</b> <b>D: Y</b>	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 09:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8K9Y	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-08-2020 09:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR8K9 <b>D:</b> Z	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 09:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8K9Z	Initial Entry

**5.d**

Date	Location	User	Value	Reason
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090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Oct-08-2020 09:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BNTL</b> <b>D: DK</b>	Initial Entry
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**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 09:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNTL DK	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-08-2020 09:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BNTL</b> <b>D: DL</b>	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-08-2020 09:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNTLDL	Initial Entry

**Header Text:** C4591001

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

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

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

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

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-08-2020 09:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-08-2020 09:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-08-2020 09:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/6/2020	Initial Entry

**5.a**

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Date	Location	User	Value	Reason
Oct-08-2020 09:36:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR8K9 <b>D:</b> C	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 09:36:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8K9C	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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

Date	Location	User	Value	Reason
Oct-06-2020 10:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-06-2020 10:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-06-2020 10:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Oct-06-2020 10:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020 10:13	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-06-2020 10:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-06-2020 10:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Oct-06-2020 10:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-06-2020 10:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 10:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-06-2020 10:20:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGE NICITY E-DIARY NOT COLLECTE D FOR THIS SUB JECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Verified

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-27-2021 13:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Jan-27-2021 13:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Verified

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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**1. Date:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Temperature:</b> Not Done <b>Temperature Unit:</b> Not Done <b>Temperature Location::</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Verified

Site No: 1232

Site Name: (1232) Columbus Regional Research Institute

Subject No: 12321299

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 17:24

(b) (4)

& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Date	Location	User	Value	Reason
Jan-27-2021 13:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1232

Site Name: (1232) Columbus Regional Research Institute

Subject No: 12321299

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 17:24

(b) (4)

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

Jan-27-2021 13:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**Header Text:** C4591001

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

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Queries, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-27-2021 13:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-27-2021 13:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-12-2021 16:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Per comment on page, please review if EOT reason was for status PHYSICIAN DECISION and

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

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

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Queries, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

				consider if subject should also be reported off study (FUP page) due to LTFU comment
Mar-12-2021 15:00:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data has been updated
Mar-12-2021 14:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: MH is unlocked as requested - please ensure any entry added is related to events/conditions prior to V1.
Mar-11-2021 14:09:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unlock Med Hx. Temporary delay was initially intended.
Mar-10-2021 13:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: For high BP - there is no adverse event entry nor prior med hx for this

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)

**Header Text:** C4591001

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

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Queries, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

				occurrence. Please review if one of the listings needs updating. Per your information was a temporary delay initially intended?
Mar-10-2021 10:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Pt blood pressure was too high to receive vaccination
Mar-10-2021 04:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Please clarify reason for lack of Vax 2 - per comment 'investigator decision'. Was any event linked to this decision?
Mar-08-2021 12:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EOT date is correct
Mar-03-2021 02:24:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please review

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)



<b>Header Text:</b> C4591001 <b>Visit:</b> End of Treatment - Unscheduled <b>Form:</b> DISPOSITION - TREATMENT - eCRF Audit Trail History <b>Form Version:</b> 10-Dec-2020 02:29 <b>Form Status:</b> Data Complete, Queries, Verified <b>Site No:</b> 1232 <b>Site Name:</b> (1232) Columbus Regional Research Institute <b>Subject No:</b> 12321299 <b>Subject Initials:</b> --- <b>Generated By:</b> (b) (4) <b>Generated Time (GMT):</b> 29-Mar-2021 17:24				
(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		reason for not administering Vax2 and select a status that matches that reason. Please also review EOT date since should match to the date of decision not to dose at Vax 2 (currently is V1 date)
Mar-02-2021 12:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candi date	CLINQUERY: Please review reason for not administering Vax2 and select a status that matches that reason. Please also review EOT date since should match to the date of decision not to dose at Vax 2 (currently is V1 date)
Jan-27-2021 13:52:01 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**Header Text:** C4591001

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

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Queries, Verified

**Site No:** 1232 **Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:24

(US & Canada)

**4. Specify Status:**

Date	Location	User	Value	Reason
Jan-27-2021 13:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject did not receive V2 vaccination due to investigator decision and was then lost to follow up	Initial Entry

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

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*1. Subject Status*

Date	Location	User	Value	Reason
Jan-27-2021 13:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-06-2020 10:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-06-2020 10:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

*2. Subject Status Date*

Date	Location	User	Value	Reason
Jan-27-2021 13:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/6/2020	Initial Entry
Oct-06-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (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:** 1232

**Site Name:** (1232) Columbus Regional Research Institute

**Subject No:** 12321299

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 17:24

(b) (4)

10:03:53 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Oct/6/2020	
Oct-06-2020 10:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1232

**Subject No:** 12321299

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1232) Columbus Regional Research Institute

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:24

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-10-2020 10:01:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae2fe8\Final\Final On: 01-Apr-2021 03:56 (GMT)