

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/6/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11121255]
2.	Birth Date:	(b) (6) 1955
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Postmenopausal]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Ovarian Cysts]
	Start Date:	UNK/UNK/1984
	Ongoing:	NO End Date: UNK/UNK/1984
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/1984
	Ongoing:	NO End Date: UNK/UNK/1984

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

HIV Status

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/6/2020
2.	Weight:	[114.4]
3.	Unit:	LB
4.	Height:	[61.0]
5.	Unit:	in
6.	Body Mass Index:	[21.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/6/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/6/2020
2.	Randomization Number:	[257794]
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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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	[BPXRZB]
5.b	Sample ID	[BPXRZC]
5.c	Sample ID	[BPXRZD]
5.d	Sample ID	[BJ4PVV]
5.e	Sample ID	[BJ4PVW]

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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	[BPXRZV]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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 10:38
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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/26/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/26/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/26/2020
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	[BMB9NM]
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done	Comments
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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:** Data Complete, Locked, Frozen, Verified

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/23/2020
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	[BMB9TL]
5.b	Sample ID	[BMPDCW]
5.c	Sample ID	[BMPDCX]

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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:	[]
----	------------------------	-----

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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	[]
----	-----------	-----

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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?	
----	--	--

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

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

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

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

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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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

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: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Unplanned Assessments

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Fever	Oct/6/2020 U NK:UNK	NO End Date Time: Oct/7/2020 UNK:U NK	Repeating Pages
2.	ADVERSE EVENT	2	Chills	Oct/6/2020 U NK:UNK	NO End Date Time: Oct/7/2020 UNK:U NK	Repeating Pages
3.	ADVERSE EVENT	3	Headache s	Oct/6/2020 U NK:UNK	NO End Date Time: Oct/7/2020 UNK:U NK	Repeating Pages
4.	ADVERSE EVENT	4	Muscle A ches	Oct/6/2020 U NK:UNK	NO End Date Time: Oct/7/2020 UNK:U NK	Repeating Pages

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever]
4.	Start Date Time:	Oct/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/7/2020 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Oct/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/7/2020 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headaches]
4.	Start Date Time:	Oct/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/7/2020 UNK:UNK
6.	Toxicity Grade:	3

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle Aches]
4.	Start Date Time:	Oct/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/7/2020 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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	[]

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Concomitant Medications

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Concomitant Medications

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Radiation Treatment

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

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

Header Text: c4591001

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

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

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Vital Signs

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

Vital Signs Details

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Lab Urinalysis

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

Lab Result

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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?	

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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	[]
----	-----------	-----

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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	[]
----	-----------	-----

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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:** Data Complete, Frozen, Verified

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

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

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/17/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Withdrawal Of Consent

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Oct/7/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Nathan Segall	Approved	Mar-06-2021 10:11:10 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, NathanSegall, 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.

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-06-2020 11:49:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
1	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
2	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
3	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
4	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
5	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
6	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
7	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
8	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
9	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
10	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> Not Done

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Item	Date	User	Comment
11	Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	subject had severe reactions after first vaccine and per PI will not receive Vaccine 2 <hr/> 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, Signed, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Nathan Segall	Approved	Mar-06-2021 10:11:10 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-25-2021 14:35:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Nathan Segall	Approved	Dec-22-2020 13:53:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Affidavit:

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

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

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

(b) (6)	N/A	Dec-17-2020 13:44:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Nathan Segall	Approved	Nov-24-2020 16:07:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, NathanSegall, 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.

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(b) (6)	N/A	Nov-23-2020 14:09:03 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Nathan Segall	Approved	Nov-14-2020 08:48:49 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-11-2020 11:06:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Nathan Segall	Approved	Nov-10-2020 16:04:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Affidavit:

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

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

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

Header Text: c4591001

Visit: 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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-06-2020 11:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 11:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Oct-06-2020 11:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/6/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-06-2020 11:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11121255	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-06-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1955	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-06-2020 11:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-06-2020 11:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Oct-06-2020 11:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-06-2020 11:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-06-2020 11:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-06-2020 11:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-06-2020 11:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1112**Site Name:** (1112) Clinical Research Atlanta**Subject No:** 11121255**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Oct-06-2020 11:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical History Term: Hypothyroidism Start Date: UNK/UNK/1970 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-06-2020 11:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 11:50:45 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypothyroidism	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, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

& Canada)				
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1.a Start Date:

Date	Location	User	Value	Reason
Oct-06-2020 11:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1970	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-06-2020 11:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-06-2020 13:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His Postmen tory Term: opausal Start Date: UNK/U NK/199 5 Ongoing: YES	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-06-2020 13:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 13:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Postmenopausal	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-06-2020 13:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-06-2020 13:36:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

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

I.c

Date	Location	User	Value	Reason
Oct-06-2020 13:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His Anxiety tory Term: Start Date: UNK/U NK/200 0 Ongoing: YES	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 13:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anxiety	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:08	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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1.d

Date	Location	User	Value	Reason
Oct-06-2020 13:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4 Number: Medical H Ovarian C istory Ter ysts m: Start Date UNK/UN : K/1984 Ongoing: NO End Date : UNK/U NK/198 4	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 13:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Ovarian Cysts	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1984	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:32	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	End Date: UNK/UNK/1984
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I.e

Date	Location	User	Value	Reason
Oct-06-2020 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number: Medical History Term: Hysterectomy m: Start Date UNK/UNK/1984 Ongoing: NO End Date : UNK/UNK/1984 4	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hysterectomy	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1984	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-06-2020 13:37:49	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	End Date: UNK/UNK/1984	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-06-2020 11:51:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 114.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 61.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-06-2020 12:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperat 97.5 ure:	Transcription Error

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			Temperat F ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperat 97.0 ure: Temperat F ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-06-2020 12:12:42 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.5	Transcription Error

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Eastern Time (US & Canada)				
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-06-2020 11:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-06-2020 11:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-06-2020 11:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-06-2020 11:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-06-2020 11:57:50 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of collection is reported, but

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Eastern Time (US & Canada)				result is missing. Please review and update as appropriate.
Oct-06-2020 11:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-06-2020 11:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-06-2020 11:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

<p>Oct-06-2020 11:58:02 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Sponsor 113 -Defined Identifier: Test:: Choriogonadotropin Beta_P X113 Result:: Not Done:: NOT DONE</p>	<p>Initial Entry</p>
<p>Oct-06-2020 11:57:50 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: Sponsor -Defined Identifier: Test:: Choriogonadotropin Beta_P X113 Result:: Not Done:</p>	<p>Initial Entry</p>

6.a Sponsor ID:

Date	Location	User	Value	Reason
<p>Oct-06-2020 11:58:02 (UTC-05:00)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: 113</p>	<p>Initial Entry</p>

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Eastern Time (US
& Canada)

6.a Test:

Date	Location	User	Value	Reason
Oct-06-2020 11:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-06-2020 11:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Oct-06-2020 11:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-06-2020 11:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 257794	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-06-2020 11:58:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-06-2020 11:58:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-06-2020 11:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-06-2020 11:58:33 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-06-2020 11:58:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-06-2020 11:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXRZ D: B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 11:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRZB	Initial Entry

5.b

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Oct-06-2020 11:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXRZ D: C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 11:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRZC	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-06-2020 11:59:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXRZ D: D	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.c Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 11:59:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRZD	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-06-2020 11:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BJ4PV D: V	Transcription Error
Oct-06-2020 11:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ4P :	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 11:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-06-2020 11:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4PVV	Transcription Error
Oct-06-2020 11:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Oct-06-2020 11:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4PV	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-06-2020 12:00:00 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BJ4PV D: W	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Eastern Time (US & Canada)

5.e Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 12:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4PVW	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-06-2020 12:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-06-2020 12:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-06-2020 12:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-06-2020 12:00:40 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-06-2020 12:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-06-2020 12:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXRZ D: V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 12:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRZV	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 10:38	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 12:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-06-2020 12:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-26-2020 15:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-26-2020 15:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: Temperature: Temperature Unit: Temperature ORAL Temperature Location: CAVIT Temperature: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:02 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 15:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-26-2020 15:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-26-2020 15:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-26-2020 15:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 15:07:22 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-26-2020 15:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-26-2020 15:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BMB9N D: M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 15:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMB9NM	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

8. Actual Dose:

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-26-2020 15:09:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Oct-26-2020 15:09:36	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

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

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-23-2020 14:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/23/2020	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-23-2020 14:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-23-2020 14:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-23-2020 14:09:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-23-2020 14:09:12 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

Site No: 1112 Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:58

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-23-2020 14:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Nov/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-23-2020 14:09:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BMB9T D: L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 14:09:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMB9TL	Initial Entry

5.b

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Nov-23-2020 14:09:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BMPDC D: W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 14:09:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPDCW	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-23-2020 14:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BMPDC D: X	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

5.c Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 14:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPDCX	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fever	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-27-2020 07:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response.
Oct-26-2020 15:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	exact time unknown, but progress note states within 5 hrs post-vaccine
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Fever: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	End Date Time: Oct/7/2020 UNK: UNK
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

090177e196ae3dfe\Final\On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 08:41:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per email 11/15/2020 query not needed
Nov-15-2020 11:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Only 1 AE should have DRUG WITHDRAWN as Action Taken. Please have the PI decide which one is most

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				appropriate.
Nov-11-2020 17:04:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 11:04:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI note, subject withdrew due to combination of reactions.
Nov-11-2020 10:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Only one primary Adverse Event should be chosen. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Nov-11-2020 08:31:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was a combination of all reactions
Nov-10-2020 22:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDR AWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chills	Initial Entry

4. Start Date Time:

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Oct-27-2020 07:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response.
Oct-26-2020 15:13:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	exact time is not known, but reported post vaccination
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Chills: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/7/2020 UNK: UNK	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 08:41:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per email 11/15/2020 query not needed
Nov-15-2020 11:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Only 1 AE should have DRUG WITHDRAWN as Action Taken. Please have the

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				PI decide which one is most appropriate.
Nov-11-2020 17:04:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.
Nov-11-2020 11:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI note, subject withdrew due to combination of reactions.
Nov-11-2020 10:25:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Only one primary Adverse Event should be chosen. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Nov-11-2020 08:31:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was a combination of all reactions
Nov-10-2020 22:22:47 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Only one primary Adverse Event should be chosen to have

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Locked, Frozen**Site No:** 1112**Site Name:** (1112) Clinical Research Atlanta**Subject No:** 11121255**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

(US & Canada)				question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDR AWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 15:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-01-2020 19:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 10:36:46	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirm, no history of

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		headaches or migraines or cluster headacheas
Oct-28-2020 21:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Headache: Please confirm that the participant does or does not have a prior medical history of migraine or cluster headaches
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headaches	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 07:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response.
Oct-26-2020 15:14:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	exact time unknown,

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)				reported post vaccine
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Headaches: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/7/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 08:41:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per email 11/15/2020 query not needed
Nov-15-2020 11:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Only 1 AE should have DRUG WITHDRAWN as Action Taken. Please have the PI decide which one is most appropriate.
Nov-11-2020 17:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Nov-11-2020 11:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI note, subject withdrew due to combination of reactions.
Nov-11-2020 10:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Only one primary Adverse Event should be chosen. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Nov-11-2020 08:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was a combination of all reactions
Nov-10-2020 22:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

				selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDR AWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-26-2020 15:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle Aches	Initial Entry

4. Start Date Time:

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Nov-06-2020 05:53:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 08:03:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirm, post vaccination, exact time unknown
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Muscle Aches: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

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Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/7/2020 UNK: UNK	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 08:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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

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

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-11-2020 15:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-11-2020 11:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	changed per query
Nov-11-2020 11:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020	changed per query
Nov-11-2020 10:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued :Opened	The page has been unfrozen. Please update the date.
Nov-11-2020 08:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	unable to update, page is locked

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Nov-10-2020 22:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	The discontinuation date of 26OCT2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 06OCT2020 and end 07OCT2020 (date should not be after the AE ended). Please adjust Discontinuation date.
Oct-29-2020 20:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-28-2020 08:11:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirm, subject called before her visit 2 to inform us she did not want to get the second vaccine due to her adverse reactions at

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

				vaccine 1
Oct-27-2020 22:10:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: subject has 3 AE's which lead to withdrawal from vaccination on 07 Oct, however, the EOT page states subject was withdrawn on 26 Oct. please review/update as appropriate. Thanks
Oct-26-2020 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-26-2020 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Oct-29-2020 00:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 09:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject is continuing in study, only discontinued from treatment
Oct-27-2020 07:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Per CRF CR 8.55.2, If Adverse Event is primary reason the Participant was discontinued from study then corresponding AE should have 'Did the adverse event cause the Participant to be discontinued from the study?' as Yes. Please review and update CRF.

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Oct-26-2020 15:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-26-2020 15:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not discontinued from study but from treatment
Oct-26-2020 15:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Oct-26-2020 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

				data.
Oct-26-2020 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVE NT	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Oct-26-2020 15:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-26-2020 15:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: due to severe reacti ons to first vaccine, subject did not rece ive second vaccine	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 14:35:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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

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

Site No: 1112 **Site Name:** (1112) Clinical Research Atlanta

Subject No: 11121255 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-25-2021 14:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccinat ion 3 Participant is: eligible and NOT confirmed to have received only plac ebo at Vaccination 1/2	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-17-2020 13:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-26-2021 01:51:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 14:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-25-2021 08:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Please review and complete the REVAX CONT visit.
Feb-24-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unlock revax cont

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

20:06:48 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	red	page for update
Feb-22-2021 22:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Puig (b) (4)	Query 1: Opened	DM: Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Dec-17-2020 13:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-26-2020 15:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-06-2020 11:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-06-2020 11:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-11-2020 11:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	changed per query
Oct-26-2020 15:10:03	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/26/2020	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (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: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121255

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-05:00) Eastern Time (US & Canada)				
Oct-06-2020 11:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/6/2020	Initial Entry
Oct-06-2020 11:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/6/2020	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121255

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-09-2020 15:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3dfe\Final\Final On: 01-Apr-2021 04:42 (GMT)