

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: COHORT_SELECTION

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](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/21/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11121337]
2.	Birth Date:	(b) (6)/1941
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:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

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/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1112

Subject No: 11121337

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
----	--	----------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1112

Subject No: 11121337

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/21/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

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](#)

Medical History Details

1.a	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Headaches, Occasional]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma, moderate]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diverticulitis]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteopenia]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis, generalized]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Irritable Bowel Syndrome]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Esophageal stricture]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes, type 2]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Meralgia Paresthetica, right thigh]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression, situational]
	Start Date:	Apr/UNK/2017
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vaginal dryness]
	Start Date:	Sep/UNK/2017
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergic rhinitis]
	Start Date:	UNK/UNK/1947
	Ongoing:	YES

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Perennial allergic rhinitis]
	Start Date:	UNK/UNK/1955
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fracture, left foot]
	Start Date:	Jan/20/2020
	Ongoing:	NO End Date: Jan/20/2020
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Surgery, left foot]
	Start Date:	Jan/20/2020
	Ongoing:	NO End Date: Jan/20/2020
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Endometriosis]
	Start Date:	UNK/UNK/1972
	Ongoing:	NO End Date: UNK/UNK/1974

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/1974
	Ongoing:	NO End Date: UNK/UNK/1974

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1112

Subject No: 11121337

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
----	---	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

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](#)

Vital Signs

1.	Date:	Oct/21/2020
2.	Weight:	[170.0]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[27.4]

Vital Signs Details

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

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1112

Subject No: 11121337

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/21/2020
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

090177e196ae3dce\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: 11121337

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/21/2020
2.	Randomization Number:	[272070]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
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	[BMPD83]
5.b	Sample ID	[BMPD84]
5.c	Sample ID	[BMB9ML]

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
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	[BMB9MX]
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090177e196ae3dce\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: 11121337

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/21/2020 17:28
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

090177e196ae3dce\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: 11121337

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
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

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: V2_VAX2_L

Form Version: 20-Feb-2021 02:16

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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:	

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

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	[]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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?	

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

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: V3_MONTH1_POSTVAX2_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: 11121337

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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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

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: 11121337

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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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

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 Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

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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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

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 Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

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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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: 11121337

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:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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_ILL - New Unscheduled Visit **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: 11121337

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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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: 11121337

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?	
----	--	--

090177e196ae3dce\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: 11121337

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: 11121337

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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 - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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:	
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090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

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: 11121337

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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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	Fatigue	Oct/22/2020 UNK:UNK	NO End Date Time: Oct/28/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Headache	Oct/22/2020 UNK:UNK	NO End Date Time: Oct/28/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Muscle Aches	Oct/22/2020 UNK:UNK	NO End Date Time: Oct/28/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Nausea	Oct/22/2020 UNK:UNK	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Diarrhea	Oct/22/2020 UNK:UNK	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Vomiting	Oct/25/2020 UNK:UNK	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Oct/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/28/2020 UNK:UNK
6.	Toxicity Grade:	2
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?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Oct/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/28/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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	[]

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Header Text: c4591001

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle Aches]
4.	Start Date Time:	Oct/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/28/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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	[]

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Header Text: c4591001

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Nausea]
4.	Start Date Time:	Oct/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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Subject No: 11121337

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diarrhea]
4.	Start Date Time:	Oct/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	3
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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Vomiting]
4.	Start Date Time:	Oct/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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	[]

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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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Medication Error

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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

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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Concomitant Medications

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

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Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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 Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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Radiation Treatment

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

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: 11121337

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 Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

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: 11121337

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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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: 11121337

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:	

090177e196ae3dce\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: 11121337

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:	

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: 11121337

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?	

090177e196ae3dce\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: 11121337

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: 11121337

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 - 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: 11121337

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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

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: 11121337

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: 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: 11121337

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: 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: 11121337

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/26/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
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: 11121337

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: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Nov/12/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	Nov/12/2020
----	------------------------------	-------------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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 Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/12/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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: 11121337

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-07-2021 20:51:05 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Oct-21-2020 15:54:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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-07-2021 20:51:05 (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-17-2021 15:27:46 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

Nathan Segall	Approved	Nov-16-2020 16:37:40 (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.

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: COHORT SELECTION - 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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-21-2020 15:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 15:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - 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

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-21-2020 15:54:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/21/2020	Initial Entry

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1112

Subject No: 11121337

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

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1. Subject ID

Date	Location	User	Value	Reason
Oct-21-2020 15:53:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11121337	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-21-2020 15:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1941	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-21-2020 15:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-21-2020 15:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 15:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3dce\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: 11121337

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-21-2020 15:54:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - 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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-21-2020 15:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-21-2020 15:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-21-2020 15:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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I.a

Date	Location	User	Value	Reason
Oct-22-2020 08:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 4 Medical History Term: Headaches, Occasional Start Date: UNK/UNK/2010 Ongoing: YES	Per subject, no hx of headaches, error (DELETED)
Oct-21-2020 17:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Headaches, Occasional Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-22-2020 08:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Per subject, no hx of headaches, error (DELETED)
Oct-21-2020 17:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 08:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headaches, Occasional	Per subject, no hx of headaches, error (DELETED)
Oct-21-2020 17:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headaches, Occasional	Initial Entry

I.a Start Date:

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Oct-22-2020 08:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Per subject, no hx of headaches, error (DELETED)
Oct-21-2020 17:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Oct-22-2020 08:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Per subject, no hx of headaches, error (DELETED)
Oct-21-2020 17:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-21-2020 17:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Asthma, moderate Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Asthma, moderate	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-21-2020 17:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Hypertension Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-21-2020 17:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 4 ber: Medical Histor Gastroesophageal re y Term: flux disease Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3dce\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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastroesophageal reflux disease	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-21-2020 17:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Diverticulitis Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:55 (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-21-2020 17:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diverticulitis	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-21-2020 17:49:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Osteopenia Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

I.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:49:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:49:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteopenia	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:49:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:49:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Oct-21-2020 17:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Hyperlipidemia Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

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Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperlipidemia	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Oct-21-2020 17:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Osteoarthritis, generalized Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11121337

Generated By: (b) (4)

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Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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I.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis, generalized	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Oct-21-2020 17:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Irritable Bowel Syndrome Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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L.i Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

L.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Irritable Bowel Syndrome	Initial Entry

L.i Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

L.i Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1112) Clinical Research Atlanta

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I.j

Date	Location	User	Value	Reason
Oct-21-2020 17:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 10 : Medical History Term: Esophageal stricture Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

I.j Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Esophageal stricture	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
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090177e196ae3dce\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

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Generated By: (b) (4)

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Oct-21-2020 17:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: Diabetes, type 2 Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry
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I.k Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes, type 2	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.l

Date	Location	User	Value	Reason
Oct-21-2020 17:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: Meralgia Paresthetica, right thigh	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

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			Start Date: UNK/UNK/2005	
			Ongoing: YES	

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Meralgia Paresthetica, right thigh	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Oct-21-2020 17:52:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 r: Medical History Term: Depression, situational Start Date: Apr/UNK/2017 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Generated By: (b) (4)

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1.m Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:52:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:52:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression, situational	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:52:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2017	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:52:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.n

Date	Location	User	Value	Reason
Oct-21-2020 17:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: Vaginal dryness Start Date: Sep/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

<i>I.n Line/MH Number:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

<i>I.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vaginal dryness	Initial Entry

<i>I.n Start Date:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2017	Initial Entry

<i>I.n Ongoing:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

<i>I.o</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History Term: Seasonal allergic rhinitis Start Date: UNK/UNK/1947 Ongoing: YES	Initial Entry

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

<i>I.o Line/MH Number:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry
<i>I.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Seasonal allergic rhinitis	Initial Entry
<i>I.o Start Date:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1947	Initial Entry
<i>I.o Ongoing:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
<i>I.p</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History: Perennial allergic rhinitis Term: rhinitis Start Date: UNK/UNK/1955 Ongoing: YES	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

<i>I.p Line/MH Number:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry
<i>I.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Perennial allergic rhinitis	Initial Entry
<i>I.p Start Date:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1955	Initial Entry
<i>I.p Ongoing:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
<i>I.q</i>				
Date	Location	User	Value	Reason
Oct-22-2020 08:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number 17 : Medical History T Fracture, left f erm: oot Start Date: Jan/20/2020 Ongoing: NO End Date: Jan/20/2020	Transcription Error
Oct-21-2020 17:54:47 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 17	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Time (US & Canada)				
				Medical History Term: Fracture, left foot Start Date: Jan/UNK/2020 Ongoing: NO End Date: Jan/20/2020

1.q Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fracture, left foot	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 08:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2020	Transcription Error
Oct-21-2020 17:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/20/2020	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

<i>I.r</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 Medical History Term: Surgery, left foot Start Date: Jan/20/2020 Ongoing: NO End Date: Jan/20/2020	Initial Entry

<i>I.r Line/MH Number:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

<i>I.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Surgery, left foot	Initial Entry

<i>I.r Start Date:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2020	Initial Entry

<i>I.r Ongoing:</i>				
Date	Location	User	Value	Reason
Oct-21-2020 17:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/20/2020	Initial Entry

I.s

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Oct-22-2020 08:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: Medical History Term: Endometriosis Start Date: UNK/UNK/1972 Ongoing: NO End Date: UNK/UNK/1974	Transcription Error
Oct-21-2020 17:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Endometriosis Start Date: UNK/UNK/1974 Ongoing: NO End Date: UNK/UNK/1974	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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I.s Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Endometriosis	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 08:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1972	Transcription Error
Oct-21-2020 17:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1974	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1974	Initial Entry

I.t

Date	Location	User	Value	Reason
Oct-21-2020 17:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 20 : Medical History T Hysterectomy erm: Start Date: UNK/UNK/1974	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Ongoing:	NO	
				End Date:	
				UNK/UNK/1974	

1.t Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 17:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hysterectomy	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1974	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 17:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1974	Initial Entry

090177e196ae3dce\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: 11121337

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

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

Date	Location	User	Value	Reason
Oct-21-2020 17:53:10 (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 Version: 10-Oct-2020 16:04

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

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1. Date:

Date	Location	User	Value	Reason
Oct-21-2020 17:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-21-2020 17:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 170.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-21-2020 17:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-21-2020 17:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 66.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-21-2020 17:53:44 (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-21-2020 17:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.4	Initial Entry

7.a

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

Date	Location	User	Value	Reason
Oct-21-2020 17:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-21-2020 17:53:44 (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-21-2020 17:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-21-2020 17:53:44 (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-21-2020 17:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3dce\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: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 17:54:11 (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-21-2020 17:54:11 (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-21-2020 17:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-21-2020 17:54:11 (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-21-2020 17:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-21-2020 17:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define d Identifier: 113	Initial Entry

090177e196ae3dce\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: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Choriogonadotropin Beta_PX113	
			Result::	
			Not Done:: NOT DONE	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 17:54:11 (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-21-2020 17:54:11 (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-21-2020 17:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3dce\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: 11121337

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-21-2020 17:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-21-2020 17:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 272070	Initial Entry

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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-21-2020 17:59:22 (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-21-2020 17:59:22 (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-21-2020 17:59:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 17:59:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 17:59:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 17:59:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMPD83	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3dce\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: 11121337
 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

Oct-21-2020 17:59:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPD83	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-21-2020 17:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMPD84	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 17:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPD84	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 18:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMB9ML	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 18:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMB9ML	Initial Entry

090177e196ae3dce\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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-21-2020 18:00:24 (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-21-2020 18:00:24 (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-21-2020 18:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 18:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 18:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 18:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMB9MX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3dce\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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Oct-21-2020 18:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMB9MX	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121337

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/21/2020 17:28	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

090177e196ae3dce\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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-21-2020 17:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - 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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-21-2020 17:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 16:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3dce\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, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 16:12:56 (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 16:12:56 (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 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 10:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-18-2021 08:21:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	sorry, not end date for symptom, end date for study. symptom date is correct.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Feb-18-2021 07:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Rei ssued: Opene d	DM 2: Per response, End date should be 12/Nov /2020. However, End date is recorded as 28/Oct/2020. Please review and update. Else, clarify.
Feb-17-2021 15:28:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	Original value is correct
Feb-17-2021 15:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Rei ssued: Opene d	DM1: Pages unlocked. please review and update appropriately.
Feb-17-2021 08:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	end date and date of withdrawal should be 12 Nov 2020, please unlock pages for update
Feb-17-2021 01:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Op ened	End Date (28Oct2020) is after Date of Completion/Discontinuation /Death (26Oct2020) on the Disposition-Follow-up eCRF. Hence, please clarify and update as ongoing if this AE was ongoing at the time subject ended the study participation. Else clarify.
Nov-03-2020 00:10:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Nov-02-2020 08:34:05 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	confirm, followed up with subject to end AE's

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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Canada)				
Oct-30-2020 15:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW5230648; 'End Date' is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Oct-30-2020 10:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO End Date Tim e: Oc t/2 8/2 02 0 U N K: U N K	New Information
Oct-28-2020 12:53:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-27-2020 10:08:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	ongoing at time of subjects withdrawal of consent
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Op ened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1112**Subject No:** 11121337**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1112) Clinical Research Atlanta**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

Nov-14-2020 16:16:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 08:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	spoke with PI, please unlock for update
Nov-12-2020 00:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : For AE# 1 to 6, Action taken with Study Treatment is recorded as "DRUG WITHDRAWN". However, Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. please update.
Nov-11-2020 08:35:35 (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 22:25:51 (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 selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

II. Was a Concomitant Medication 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, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 16:12:56 (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
Oct-30-2020 10:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-30-2020 10:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-30-2020 10:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Fatigue: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-15-2020 23:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-14-2020 22:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-14-2020 22:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Nov-14-2020 15:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	duplicate
Nov-14-2020 15:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if applicable. Please chose Primary Adverse Event.
Nov-14-2020 15:33:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if applicable. Please chose Primary Adverse Event.
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 10:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-27-2020 10:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

Oct-26-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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090177e196ae3dce\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: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 16:13:49 (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 16:13:49 (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 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-26-2020 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 10:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-18-2021 08:21:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	sorry, not end date for symptom, end date for study. symptom date is correct.

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
Feb-18-2021 02:26:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM : Per response, End date should be 12/Nov /2020. However, End date is recorded as 28/Oct/2020. Please review and update. Else, clarify.
Feb-17-2021 15:29:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Feb-17-2021 15:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM1: Pages unlocked. please review and update appropriately.
Feb-17-2021 08:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	end date and date of withdrawal should be 12 Nov 2020, please unlock pages for update
Feb-17-2021 01:01:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Opened	End Date (28Oct2020) is after Date of Completion/Discontinuation /Death (26Oct2020) on the Disposition-Follow-up eCRF. Hence, please clarify and update as ongoing if this AE was ongoing at the time subject ended the study participation. Else clarify.
Nov-04-2020 00:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-02-2020 08:34:16 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	confirm, followed up with subject to end AE's

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

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Eastern Time (US & Canada)				
Oct-30-2020 15:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW5230649; 'End Date' is after 'Date of Completion/Discontinuation/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Oct-30-2020 10:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO End Date Time: Oct/28/2020 UNKN UNK	Transcription Error
Oct-28-2020 12:55:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 10:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ongoing at time of subjects withdrawal of consent
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
Oct-26-2020 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Nov-14-2020 16:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-14-2020 08:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-14-2020 08:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Nov-13-2020 22:12:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Per previous query response, AE # 2 Headache has been unfrozen. Please consider to amend the data as appropriate else clarify.
Nov-12-2020 08:10:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	spoke with PI, unlock for update
Nov-12-2020 02:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Please consider to update. Else; clarify.
Nov-11-2020 08:35:46 (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 22:26:11 (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 selected

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				at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 16:13:49 (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 16:13:49 (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
Oct-30-2020 10:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-30-2020 10:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-30-2020 10:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Headache: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-26-2020 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
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Nov-15-2020 23:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-14-2020 22:00:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Nov-14-2020 22:00:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Nov-14-2020 15:37:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study? answered as YES if applicable. Please chose Primary Adverse Event.
Oct-29-2020 02:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-28-2020 18:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	value is correct, per subject, its the combination of all the reactions from the vaccine that caused her to withdraw
Oct-28-2020 13:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Only one 1 AE should cause discontinuation from study. Please review and update response for appropriate AE; else clarify.
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 10:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct

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Oct-27-2020 10:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Oct-27-2020 10:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-27-2020 10:02:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error

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Header Text: c4591001

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Subject No: 11121337

Generated By: (b) (4)

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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 16:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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Subject No: 11121337

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 16:14:38 (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
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Muscle Aches	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 10:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-18-2021 08:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	sorry, not end date for symptom, end date for study. symptom date is correct.

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Canada)				
Feb-18-2021 01:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM 2: Per response, End date should be 12/Nov /2020. However, End date is recorded as 28/Oct/2020. Please review and update. Else, clarify.
Feb-17-2021 15:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Feb-17-2021 15:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM1: Pages unlocked. please review and update appropriately.
Feb-17-2021 08:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	end date and date of withdrawal should be 12 Nov 2020, please unlock pages for update
Feb-17-2021 01:01:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Opened	End Date (28Oct2020) is after Date of Completion/Discontinuation /Death (26Oct2020) on the Disposition-Follow-up eCRF. Hence, please clarify and update as ongoing if this AE was ongoing at the time subject ended the study participation. Else clarify.
Nov-04-2020 06:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-02-2020 08:34:29 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	confirm, followed up with subject to end AE's

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Subject Initials: ---

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Eastern Time (US & Canada)				
Oct-30-2020 15:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW5230650; 'End Date' is after 'Date of Completion/Discontinuation/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Oct-30-2020 10:47:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO End Date Time: Oct/28/2020 UNKN UNK	New Information
Oct-28-2020 12:54:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 10:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ongoing at time of subjects withdrawal of consent
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.

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Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Nov-14-2020 16:16:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-14-2020 08:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-14-2020 08:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	New Information
Nov-14-2020 00:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM 1: Form is unfrozen. Please review and update the data per previous query. Thank you.
Nov-12-2020 08:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unlock for update
Nov-12-2020 02:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Please consider to update. Else; clarify.
Nov-11-2020 08:35:59 (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 22:26:30 (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 selected at this time, please select ONLY Primary

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

				Adverse Event.
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 16:14:38 (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 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 10:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-30-2020 10:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-30-2020 10:47:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Muscle Aches: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-26-2020 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 03:24:46 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
Nov-14-2020 22:00:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-14-2020 22:00:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Nov-14-2020 15:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if applicable. Please chose Primary Adverse Event.
Oct-29-2020 02:45:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-28-2020 18:58:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	value is correct, per subject, its the combination of all the reactions from the vaccine that caused her to withdraw
Oct-28-2020 13:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Only one 1 AE should cause discontinuation from study. Please review and update response for appropriate AE; else clarify.
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 10:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Oct-27-2020 10:03:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	More than 1 AE for this patient has "Did the adverse event

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				cause the subject to be discontinued from the study?" marked as 'Yes'.
Oct-27-2020 10:03:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-27-2020 10:03:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information

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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 16:14:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 16:15:17 (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 16:15:17 (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
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: Nausea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 13:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-05-2021 10:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Mar-04-2021 09:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Nausea should have trigger a COVID Illness visit regardless of reason. Please enter as a PD.
Mar-04-2021 08:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no covid illness, vaccine reaction
Mar-04-2021 02:46:28	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY:

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		Nausea should have trigger a COVID Illness visit. Please clarify if one was done. If not please record as PD.
Mar-03-2021 19:09:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Nausea should have trigger a COVID Illness visit. Please clarify if one was done. If not please record as PD.
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 10:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-27-2020 10:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UNK:UNK	New Information
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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Generated By: (b) (4)

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(US & Canada)		(b) (4), (b) (6)	
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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 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-14-2020 08:21:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-14-2020 08:21:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Changed Information
Nov-14-2020 07:36:27 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Only one primary Adverse

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Time (US & Canada)		(b) (4), (b) (6)		Event should be chosen please update.
Nov-11-2020 08:36:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 1: Answered	It was a combination of all reactions
Nov-10-2020 22:26:48 (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 selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 12:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 10:09:28 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ongoing at time of subjects withdrawal of

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Time (US & Canada)		(b) (4), (b) (6)		consent
Oct-27-2020 10:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Nausea: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 03:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-14-2020 22:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-14-2020 22:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Nov-14-2020 15:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if applicable. Please chose Primary Adverse Event.
Oct-29-2020 02:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-28-2020 18:58:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	value is correct, per subject, its the combination of all the reactions from the vaccine that caused her to withdraw

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Oct-28-2020 13:04:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Only one 1 AE should cause discontinuation from study. Please review and update response for appropriate AE; else clarify.
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 10:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Oct-27-2020 10:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Oct-27-2020 10:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-27-2020 10:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-26-2020 16:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

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Oct-26-2020 16:16:02 (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 16:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 16:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-26-2020 16:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 10:48:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UNK:UNK	Transcription Error
Oct-28-2020 12:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 10:09:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ongoing at time of subjects withdrawal

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Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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Time (US & Canada)		(b) (4), (b) (6)		of consent
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-26-2020 16:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 16:16:02 (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 16:16:02 (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 16:16:02 (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 16:16:02 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

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(US & Canada)		(b) (4), (b) (6)	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-14-2020 08:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-14-2020 08:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	New Information
Nov-13-2020 02:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM 1: Action taken with Study Treatment is recorded as "DRUG WITHDRAWN". However, Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. please update.
Nov-12-2020 08:08:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Nov-12-2020 07:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. please update.
Nov-11-2020 08:36:22	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was a combination

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

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)		of all reactions
Nov-10-2020 22:27:10 (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 selected at this time, please select ONLY Primary Adverse Event.
Oct-26-2020 16:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 16:16:02 (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 16:16:02 (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
Oct-30-2020 10:48:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-30-2020 10:48:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Oct-30-2020 10:48:05 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Diarrhea: Response to "What was

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-26-2020 16:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 03:24:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-14-2020 22:01:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Nov-14-2020 15:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if applicable. Please chose Primary Adverse Event.
Oct-29-2020 02:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-28-2020 18:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	value is correct, per subject, its the combination of all the reactions from the vaccine that caused her to withdraw
Oct-28-2020 13:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Only one 1 AE should cause discontinuation from study. Please review and update response for appropriate AE;

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

				else clarify.
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 10:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Oct-27-2020 10:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Oct-27-2020 10:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-27-2020 10:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-26-2020 16:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (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 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vomiting	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)		(b) (4), (b) (6)	
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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 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-14-2020 04:50:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-13-2020 08:11:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-13-2020 08:11:54	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLI	Changed Information

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Header Text: c4591001

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Subject Initials: ---

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(UTC-05:00) Eastern Time (US & Canada)			CABLE	
Nov-13-2020 02:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM : Form is unfrozen now. Please review and update the data as appropriate as per previous query. Thank you.
Nov-12-2020 08:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	unlock for update
Nov-12-2020 07:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. please update.
Nov-11-2020 08:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	It was a combination of all reactions
Nov-10-2020 22:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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				Multiple are selected at this time, please select ONLY Primary Adverse Event.
Oct-28-2020 13:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 21:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	No need to raise this query.
Oct-27-2020 21:24:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	ClinQuery: Subject listed to have drug withdrawn due to multiple AE's, however, the EOT page is not completed. Please review/update as appropriate. Thanks
Oct-27-2020 10:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-27-2020 05:20:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify. (b) (4)

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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				(b) (4)
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WIT HDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 16:16:45 (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
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 03:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-14-2020 22:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-14-2020 22:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Nov-14-2020 15:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'Did the

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Header Text: c4591001

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

				adverse event cause the subject to be discontinued from the study? answered as YES if applicable. Please chose Primary Adverse Event.
Oct-29-2020 02:46:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-28-2020 18:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	value is correct, per subject, its the combination of all the reactions from the vaccine that caused her to withdraw
Oct-28-2020 13:04:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Only one 1 AE should cause discontinuation from study. Please review and update response for appropriate AE; else clarify.
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 10:05:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Oct-27-2020 10:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Oct-27-2020 10:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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				nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-27-2020 10:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-26-2020 16:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-27-2020 10:05:53 (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-27-2020 10:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 10:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Transcription Error
Oct-27-2020 10:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-27-2020 10:06:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-27-2020 10:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Oct-27-2020 10:05:53 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Status is selected as "WITHDRAWAL BY

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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: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				SUBJECT" and WITHDRAWAL OF CONSENT form is not initiated. Please review and update as appropriate.
Oct-27-2020 10:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WITHDRAWAL BY SUBJECT	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Oct-27-2020 10:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-27-2020 10:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: subject withdrew due to adverse events related to vaccination	Initial Entry

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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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I. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-18-2021 14:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Feb-18-2021 09:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	this has been updated
Feb-18-2021 08:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	DM1: form is Unfreed. Please check and update as appropriate. Thank you.
Feb-17-2021 15:28:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	unlock withdrawal of consent for update
Feb-17-2021 15:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Date of Completion/Discontinuation /Death on the Follow-Up Disposition form is after "Withdrawal of consent" date. Please review and correct as appropriate.
Feb-17-2021 15:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Deleted	Transcription Error
Feb-17-2021 15:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/12/2020	Transcription Error
Feb-17-2021 15:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Candidate	Do not lock. Pending Date update per query on AE log form
Nov-18-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Closed	Response satisfies query
Nov-18-2020 09:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Yes, the adverse events should be ongoing at time of discontinuation.
Nov-18-2020 01:02:45 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM : Thanks for the response. However, Some

090177e196ae3dce\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1112**Subject No:** 11121337**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1112) Clinical Research Atlanta**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

Time (US & Canada)		(b) (4), (b) (6)		AE has end date as 28Oct2020, hence please update this date to 28Oct2020 or confirm whether the AEs which has stop date after 26Oct2020 should be marked as ongoing at the time of discontinuation from study.
Nov-17-2020 07:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	adverse events were ongoing when subject withdrew consent, ended after end date
Nov-17-2020 04:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Opened	Some AE has end date as 28Oct2020, hence please verify and update this date to 28Oct2020 or confirm whether the AEs which has stop date after 26Oct2020 should be marked as ongoing at the time of discontinuation from study. Else clarify.
Nov-16-2020 22:23:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-16-2020 09:26:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Nov-16-2020 09:26:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Changed Information
Nov-15-2020 00:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Closed	Response satisfies query
Nov-15-2020 00:32:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Reissued:Opened	Page unlocked
Nov-14-2020 08:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	page is locked
Nov-14-2020 08:35:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Completion/Discontinuation

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1112

Site Name: (1112) Clinical Research Atlanta

Subject No: 11121337

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				/Death on the Follow-Up Disposition form is after "Withdrawal of consent" date. Please review and correct as appropriate.
Nov-14-2020 08:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-14-2020 08:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020	Transcription Error
Nov-14-2020 05:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Some AE has end date as 28Oct2020, hence please verify and update this date to 28Oct2020. Else clarify.
Oct-27-2020 10:06:31 (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-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-01-2020 19:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-29-2020 10:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-29-2020 10:37:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Oct-29-2020 10:37:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

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Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1112**Subject No:** 11121337**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1112) Clinical Research Atlanta**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

Oct-29-2020 10:37:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Changed Information
Oct-28-2020 20:35:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	ClinQuery: Subject status for disposition states withdrawal by subject, however, the EOT page states the primary reason for discontinuation was an AE. Please update to as appropriate. Thanks
Oct-27-2020 10:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WITHDRAWAL BY SUBJECT	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Nov-01-2020 19:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 10:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-29-2020 10:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-28-2020 20:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Subject status for disposition states withdrawal by subject, but there are multiple AE's that appear to have lead to discontinuation. What

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

				was the primary reason for discontinuation? Please update to capture this information. Thanks
Oct-27-2020 10:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject no longer wishes to remain in study	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-18-2021 09:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/12/2020	Transcription Error
Nov-18-2020 11:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Closed	Response satisfies query
Nov-18-2020 11:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Deleted	Query is invalid or does not apply
Nov-17-2020 07:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	confirm, adverse events ended after subject withdrew consent.
Nov-17-2020 04:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Some adverse events have end date recorded as 28Oct2020. But subject withdrew consent on 26Oct2020. Please clarify whether the withdrew consent is correct as entered and AE end date details collected after subject's consent withdrawal from study.
Nov-15-2020 00:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Candidate	site to update the date as 28Oct2020 based on query response in EOT CRF.
Oct-27-2020 10:06:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

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Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1112**Subject No:** 11121337**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1112) Clinical Research Atlanta**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**I. Subject Status**

Date	Location	User	Value	Reason
Oct-29-2020 10:37:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Transcription Error
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-27-2020 10:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-21-2020 17:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-21-2020 15:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-17-2021 15:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/12/2020	Transcription Error
Nov-16-2020 09:26:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/26/2020	Changed Information
Nov-14-2020 08:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/28/2020	Transcription Error
Oct-29-2020 10:37:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/26/2020	Changed Information
Oct-27-2020 10:11:31 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/26/2020	Transcription Error

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1112

Subject No: 11121337

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1112) Clinical Research Atlanta

Subject Initials: ---

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

(US & Canada)				
Oct-27-2020 10:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/26/2020	Initial Entry
Oct-27-2020 10:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/26/2020	Initial Entry
Oct-21-2020 17:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/21/2020	Initial Entry
Oct-21-2020 15:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/21/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1112

Subject No: 11121337

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 10:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

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