

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Cohort Selection

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

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/17/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11621128]
2.	Birth Date:	(b) (6)/1983
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/17/2020
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: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gun shot wound]
	Start Date:	May/UNK/2016
	Ongoing:	NO End Date: May/UNK/2016
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Exploratory Abdominal Surgery]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/17/2020
2.	Weight:	[111.5]
3.	Unit:	kg
4.	Height:	[177.0]
5.	Unit:	cm
6.	Body Mass Index:	[35.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/17/2020
2.	Randomization Number:	[52825]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**[eCRF Audit Trail History](#)****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
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	[BP3J7R]
5.b	Sample ID	[BP3J7S]
5.c	Sample ID	[BP3J7T]
5.d	Sample ID	[BPLNYY]
5.e	Sample ID	[BPLNYZ]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
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	[BP3J7P]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/17/2020 13:19
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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/9/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
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	[BP8CZL]
-----	-----------	----------

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/9/2020 16:33
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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/13/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
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	[BLFV5Z]
5.b	Sample ID	[BLFV60]
5.c	Sample ID	[BPYRPR]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Health Care Utilization

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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Health Care Utilization

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Illness Details

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Unplanned Assessments

1.	Assessments	
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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Disposition - Follow-Up

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

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

Site No: 1162 **Site Name:** (1162) Atlanta Center for Medical Research

Subject No: 11621128 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 12:23

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Exposure during pregnancy	Sep/UNK/2020 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during pregnancy]	
4.	Start Date Time:	Sep/UNK/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments
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	

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Pregnancy]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Medication Error

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Radiation Treatment

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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?	

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

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

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

Site No: 1162 **Site Name:** (1162) Atlanta Center for Medical Research

Subject No: 11621128 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 12:23

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Further Vaccination Confirmation

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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/13/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Robert Riesenber	Approved	Nov-17-2020 08:08:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, RobertRiesenber, 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.

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-18-2020 11:00:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
6	Nov-16-2020 08:51:29 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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
Robert Riesenberg	Approved	Nov-17-2020 08:08:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Nov-16-2020 08:51:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Riesenberg	Approved	Nov-13-2020 14:08:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Affidavit:

By my dated signature below, I, RobertRiesenberg, 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) [Redacted]	N/A	Nov-13-2020 11:39:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Riesenberg	Approved	Nov-10-2020 15:36:50 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, RobertRiesenberg, 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) [Redacted]	N/A	Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Affidavit:

N/A

Robert Riesenberg	Approved	Oct-23-2020 15:44:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-18-2020 11:00:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:00:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-18-2020 11:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-18-2020 11:00:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11621128	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-18-2020 10:59:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1983	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-18-2020 11:00:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-18-2020 11:00:34	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	LATINO(A) OR OF SPANISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-18-2020 11:00:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERICAN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-21-2020 10:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated as per query.
Aug-20-2020 12:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-20-2020 06:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	IVRS Reconciliation: Randomization date and randomization number recorded at Impala but not recorded at Inform. Please review and update data as appropriate. Else, clarify. Thank you.
Aug-18-2020 11:00:51 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

& Canada)				
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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-18-2020 11:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-18-2020 11:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-18-2020 11:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-18-2020 11:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Gun shot wound Start Date: May/UNK/2016 Ongoing: NO End Date: May/UNK/2016	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:04:12 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gun shot wound	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Eastern Time (US & Canada)				
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1.a Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 11:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/UNK/2016	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 11:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: May/UNK/2016	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-18-2020 11:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Exploratory A T bdominal Sur erm: gery Start Date: UNK/UNK/20 16	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Ongoing: NO End Date: UNK/UNK /2016	
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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:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-18-2020 11:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exploratory Abdominal Surgery	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 11:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 11:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

& Canada)

UNK/UNK/2016

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 111.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-18-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

11:07:31 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	177.0	
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5. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperatu 36.9 re: Temperatu C re Unit:	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Temperatu ORAL re Locatio CAVIT n:: Y	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Aug-18-2020 11:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-20-2020 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 52825	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 11:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 11:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 04:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-26-2020 14:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Aug-21-2020 07:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued: Opened	DM: The barcode is not entered in a correct field. To enter barcode, Click on Add Entry button to add individual Sample ID details. Please follow section "8.11.4. Sample ID:" of CRF-CR.
Aug-20-2020 12:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Changed data per query
Aug-19-2020 09:51:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 11:08:00 (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

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				and correct as appropriate.
Aug-18-2020 11:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 04:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-26-2020 14:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-26-2020 14:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-21-2020 06:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM : Bar Code needs to be recorded in the specified area under Sample

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				ID. Please consider updating data in the appropriate field, Thank you.
Aug-20-2020 12:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3J7R BP3J7S BP3J7T BPLNYY BPLN YZ	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 14:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3J7R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 14:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3J7R	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Aug-26-2020 14:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3J7S	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 14:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3J7S	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 14:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3J7T	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 14:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3J7T	Initial Entry

5.d

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Aug-26-2020 14:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLNYY	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 14:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLNYY	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-26-2020 14:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLNYZ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 14:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLNYZ	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 11:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 11:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 04:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-26-2020 14:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Aug-21-2020 07:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: The barcode is not entered in a correct field. To enter barcode, Click on Add Entry button to add individual Sample ID details. Please follow section "8.11.4. Sample ID:" of CRF-CR.
Aug-20-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-19-2020 09:51:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 11:08:08 (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

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				and correct as appropriate.
Aug-18-2020 11:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 04:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-26-2020 14:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-26-2020 14:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-21-2020 06:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM : Bar Code needs to be recorded in the specified area under Sample

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				ID. Please consider updating data in the appropriate field, Thank you.
Aug-20-2020 12:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3J7P	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 14:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3J7P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 14:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3J7P	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-20-2020 12:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-20-2020 12:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020 13:19	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:56 (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
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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Aug-20-2020 12:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-20-2020 12:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-18-2020 11:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 15:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 15:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 37.1 Temperature C Unit: Temperature FORE Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Sep-10-2020 15:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-10-2020 15:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 15:37:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 15:37:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 15:37:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 15:37:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				review and correct as appropriate.
Sep-10-2020 15:37:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 15:37:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8CZL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 15:37:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8CZL	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:08	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 16:33	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 15:38:08 (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
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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Sep-10-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECI FIED OBSERVATION P ERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-10-2020 15:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-10-2020 02:10:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 18:13:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated
Nov-08-2020 19:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020423445 pregnancy partner(onset date:01Sep2020)was reported in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-14-2020 15:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/20 20	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 15:17:08 (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-14-2020 15:17:08 (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-14-2020 15:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 15:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

				review and correct as appropriate.
Oct-14-2020 15:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 15:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLFV5Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLFV5Z	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 15:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLFV60	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLFV60	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 15:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYRPR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYRPR	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-14-2020 15:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 15:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 15:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (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
Nov-18-2020 21:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	acceptable discrepancy
Nov-17-2020 19:55:46 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candi	Pending SDB update

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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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(US & Canada)			date	
Nov-17-2020 17:20:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed, updated report has been submitted.
Nov-16-2020 15:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	AEM = updated SAE form. Please confirm if a follow up AEM form was submitted to update term in Safety database.
Nov-16-2020 15:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify what AEM form is.
Nov-14-2020 10:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	SAE RECON 1: Thank you for the update. Please confirm if a follow up AEM form was submitted to update term in Safety database.
Nov-13-2020 11:39:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Nov-13-2020 11:39:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Exposure during pregnancy	Transcription Error
Nov-13-2020 06:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020423445,event term was reported as PREGNANT PARTNER in both database.As per V10 CRF CG 8.50.2.5 that the event should be reported as "exposure during pregnancy". Please confirm and update accordingly.
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Pregnant partner	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2020 UN K:UNK	Initial Entry

5. Is the adverse event still ongoing?

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (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
Nov-16-2020 15:38:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 08:51:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-16-2020 08:51:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-16-2020 08:51:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Nov-15-2020 01:39:09	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Toxicity grade is not expected for

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)				pregnancy related adverse events, hence please remove the toxicity and add item level comment as NOT APPLICABLE.
Nov-09-2020 18:11:14 (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
Nov-14-2020 10:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	downgraded to non serious
Nov-13-2020 11:40:26 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Del eted	Close Auto Query

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Eastern Time (US & Canada)				
Nov-13-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Nov-13-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Transcription Error
Nov-13-2020 11:39:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Exposure during pregnancy : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-10-2020 08:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020423445,'PREGNANT PARTNER', event was appropriately reported to safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Nov-10-2020 08:26:54 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query can be addressed internally

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Eastern Time (US & Canada)				
Nov-09-2020 18:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Clo sed	Close Auto Query
Nov-09-2020 18:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : YES Is thi s seri ous e vent assoc iated with cong enita l ano maly or bi rth d efect ? NO Did t his s eriu s eve	Transcription Error

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

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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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			y? NO Is this serious event life threatening? NO Other medically important serious event YES	
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Pregnant partner: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-09-2020 18:11:14 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Eastern Time (US & Canada)				NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p>	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

			Did this serious event require or prolong hospitalization? NO	
			Did this serious event result in persistent or significant disability/incapacity? NO	
			Is this seri	

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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			ous e vent life t hreat enin g? NO Othe r me dical ly im porta nt se rious event NO	
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8. Is this adverse event the result of a study Medication Error?

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

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Pregnancy
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (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
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Date	Location	User	Value	Reason
Nov-14-2020 10:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 16:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-13-2020 11:44:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Nov-13-2020 11:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Exposure during pregnancy : Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-13-2020 11:44:02	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (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:** 1162**Site Name:** (1162) Atlanta Center for Medical Research**Subject No:** 11621128**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)				
Nov-13-2020 11:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Changed Information
Nov-11-2020 05:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020423445, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Based on the latest EDP guidance, outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Nov-09-2020 18:12:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 18:11:14 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1162

Site Name: (1162) Atlanta Center for Medical Research

Subject No: 11621128

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-14-2020 15:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-20-2020 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMI ZED	Initial Entry
Aug-18-2020 11:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-14-2020 15:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	Initial Entry
Aug-20-2020 12:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae2f8e\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Canada)				
Aug-18-2020 11:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1162

Subject No: 11621128

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1162) Atlanta Center for Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 15:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry