

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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/21/2020
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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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11561015]
2.	Birth Date:	(b) (6)/1994
3.	Sex:	FEMALE
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:	

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

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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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/21/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

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:	[Seafood Allergy]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/21/2020
2.	Weight:	[69.1]
3.	Unit:	kg
4.	Height:	[171.8]
5.	Unit:	cm
6.	Body Mass Index:	[23.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/21/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/21/2020
2.	Randomization Number:	[61147]
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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1856]
5.b	Sample ID	[BP1857]
5.c	Sample ID	[BP1858]
5.d	Sample ID	[BPHRXN]
5.e	Sample ID	[BPHRXP]

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1859]
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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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/21/2020 16:05
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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

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
----	---	---

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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	Sep/28/2020
2.	Erroneous Visit	

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/28/2020
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Vital Signs Details

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/28/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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/28/2020
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	[BP18SR]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done	Comments
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **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/26/2020
2.	Erroneous Visit	

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **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/26/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR69NC]
5.b	Sample ID	[BRZPRZ]
5.c	Sample ID	[BRZPS0]

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

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 Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

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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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

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 Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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

Health Care Utilization

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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:	

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

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

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: c4591001

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

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **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 :	Sep/28/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	PREGNANCY
4.	Specify Status:	[]

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **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	[]
----	-----------	-----

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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	Aug/21/2020 12:25	YES	Repeating Pages

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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[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:	Aug/21/2020 12:25	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [THERE IS NOT AN UNDERLYING CAUSE. THIS EVENT IS A STANDARD PREGNANCY.]	Comments

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	
13.	What was the outcome of this adverse event?:	UNKNOWN	Comments
14.	Did the adverse event cause the subject to be discontinued from the study?	NO	
15.	Serious Adverse Event Number: For Pfizer Use Only	[]	

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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Medication Error

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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:	

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

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

Lab Result

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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?	

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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 - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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	Feb/18/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/18/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	---	--

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Screening for Further Vaccination

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/28/2020

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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
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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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
Hector Rodriguez	Approved	Feb-19-2021 12:16:38 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-21-2020 17:05:42 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
6	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
7	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
8	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
10	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
11	Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Done

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
6	Oct-05-2020 13:32:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
9	Oct-28-2020 18:36:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
9	Oct-05-2020 13:33:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
13	Nov-11-2020 17:37:13 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	
13	Oct-05-2020 13:33:28 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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
Hector Rodriguez	Approved	Feb-19-2021 12:16:38 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HectorRodriguez, 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.

Hector Aguilar	N/A	Feb-18-2021 17:08:06 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Hector Rodriguez	Approved	Nov-16-2020 15:33:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

By my dated signature below, I, HectorRodriguez, 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.

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-21-2020 17:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 17:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

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-21-2020 17:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Aug/21/2020	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-06-2020 07:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Event recorded in Inform
Oct-05-2020 13:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS HAS NOW BEEN ENTERED
Oct-03-2020 09:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020377626 a NON SERIOUS EXPOSURE DURING PREGNANCY event(Onset date:29Sep2020)was reported to Pfizer Safety but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-21-2020 17:03:17	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Item copied from previous form

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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

1156101
5

2. Birth Date:

Date	Location	User	Value	Reason
Aug-21-2020 17:03:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1994	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-21-2020 17:04:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-21-2020 17:04:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-21-2020 17:04:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BLACK OR AFRIC AN AMERICAN	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-21-2020 17:04:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/21/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-21-2020 17:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-21-2020 17:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-21-2020 17:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561015**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Aug-21-2020 17:07:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical History Term: Seafood Allergy Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 17:07:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 16:01:09 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query

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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Oct-05-2020 13:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS HAS NOW BEEN ENTERED
Oct-04-2020 18:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Pregnancy is to be reported as an AE regardless of whether it is associated with an AE, per CRF completion requirements section 8.47.2.5. Please update accordingly.
Aug-21-2020 17:07:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Seafood Allergy	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 17:07:24 (UTC-05:00)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: UNK/UNK/2010	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 17:07:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 69.1	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 171.8	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.4	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Record Identifier: Temperature: 97.3	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

			Temperature Unit: Temperature Location: ORAL CAVITY Y
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 97.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: F	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/21/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-21-2020 17:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-21-2020 17:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 61147	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 17:09:51 (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-21-2020 17:09:51 (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-21-2020 17:10:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 17:09:51 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Aug/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 17:10:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP185 : 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 17:10:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP1856	Initial Entry

5.b

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-21-2020 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP185 : 7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP1857	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 17:10:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP185 : 8	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 17:10:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP1858	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 17:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample I BPHRX D: N	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 17:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BPHRXN	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-21-2020 17:10:39	ACV0PFEINFP6000	Hector Aguilar	Data Entry: Sample I BPHRX	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-21-2020 17:10:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BPHRXP	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 17:10:56 (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-21-2020 17:10:56 (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-21-2020 17:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 17:10:56 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 17:10:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Aug/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 17:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP185 : 9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 17:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP1859	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-21-2020 17:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-21-2020 17:09:18 (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-21-2020 17:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Aug-21-2020 17:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/21/2020 16:05	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-21-2020 17:09:18 (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-21-2020 17:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-21-2020 17:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-21-2020 17:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 17:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-24-2020 10:11:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO - REACTOGE NICITY E-DIARY NOT COLLECTE D FOR THIS SUBJ ECT	Transcription Error
Aug-21-2020 17:09:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES - REACTOGE NICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 08:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per site confirmation - updated PD tracker
Sep-29-2020 09:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 2: Answered	subject was/is out of window
Sep-29-2020 05:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ: DOV at this visit is out of window (15 day) from DOV (21/Aug/2020) at V1D1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate.

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Sep-28-2020 17:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/28/2020	Initial Entry
Sep-28-2020 03:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-27-2020 14:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answer ed	VISIT HAS NOT BEEN COMPLETED
Sep-26-2020 06:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-28-2020 17:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Record Identifier:: Temperature: 98.2 Temperature Unit: Temperature Location: ORAL Temperature Unit: CAVIT Temperature Unit: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:34 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 1	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-04-2020 18:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Query placed on a different form.
Oct-01-2020 14:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Pregnancy is to be reported as an AE regardless of whether it is associated with an AE, per CRF completion requirements section 8.47.2.5. Please update

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

				accordingly.
Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/28/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

6.a

Date	Location	User	Value	Reason
Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: POSITIVE Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-28-2020 17:26:42 (UTC-05:00)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US
& Canada)

6.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 05:06:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker
Sep-28-2020 17:33:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	subject had a positive pregnancy test on visit 2 (28sep2020). Per PI, based on exclusion 11, subject will not receive treatment (2nd vaccine).
Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Lab result is "Positive", but subject has been vaccinated. Please review and update as appropriate. Else explain.

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Sep-28-2020 17:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: POSITIVE	Initial Entry
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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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-28-2020 18:40:01 (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-28-2020 18:40:01 (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-28-2020 18:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 18:40:01 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-28-2020 18:40:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Sep/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 18:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP18S : R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP18SR	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

8. Actual Dose:

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 17:30:47	ACV0PFEINFP6000	Hector Aguilar	Data Entry: Not Done	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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

(b) (4)

Header Text: c4591001

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

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-26-2020 16:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Oct/26/2020	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-26-2020 18:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-26-2020 18:24:10 (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-26-2020 18:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 18:24:10 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156 Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015 Subject Initials: ---

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-26-2020 18:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Oct/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-26-2020 18:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BR69N : C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 18:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BR69NC	Initial Entry

5.b

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-27-2020 09:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BRZPR : Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 09:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BRZPRZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 09:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BRZPS : 0	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 09:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BRZPS0	Initial Entry

Header Text: c4591001

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

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-28-2020 17:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-28-2020 17:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-14-2020 05:21:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Cl osed	Response satisfies query
Nov-13-2020 16:09:39 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swered	"Disposition Form Statuses for Pregnancies: If

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

Eastern Time (US & Canada)				exposure during pregnancy is the reason for treatment discontinuation: Latest Action Taken with Study Treatment = Drug Withdrawn Disposition status = Pregnancy"
Nov-12-2020 01:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Re issued:Open ed	DM 1 : Please review and consider to update the status to ADVERSE EVENT . Else,clarify.
Nov-11-2020 14:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swered	THIS REQUEST IS STILL PENDING CLARIFICATION FROM THE STUDY TEAM
Nov-07-2020 13:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Re issued:Open ed	DM Query: Please update the status to AE as it is the correct option.
Oct-27-2020 07:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Re issued:Cand idate	Added to DM Ops Tracker.
Oct-26-2020 16:20:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swered	THIS PREGNANCY DOES NOT HAVE

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **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)		AN ASSOCIATED ADVERSE EVENT. IT IS ONLY REPORTED FOR TRACKING PURPOSES. PLEASE CLOSE THIS QUERY.
Oct-26-2020 07:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Re issued:Open ed	DM: Per CCG 'Select Adverse Event if this is the primary reason the Participant was discontinued from study. This information must be consistent with the data on the Adverse Event page' Kindly review and update.
Oct-16-2020 08:31:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Re issued:Cand idate	Status needs to be updated to AE.
Oct-15-2020 14:39:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 2: An swered	THE REASON FOR END OF TREATMENT WAS AE(PREGNANCY)
Oct-14-2020 12:29:09	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Re issued:Open	DM1: As per CRF CR Section 8.55.2, If

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Header Text: c4591001**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561015**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)			ed	there are two or more reasons for withdrawal and an adverse event is one of them, the adverse event is considered the primary reason. Kindly update data accordingly, else clarify, Thank you.
Oct-12-2020 15:50:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	THAT IS BECAUSE THE TREATMENT DISCONTINUATION FORM HAS AN OPTION OF "PREGNANCY."
Oct-12-2020 15:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-12-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is PREGNANCY but "Specify Status" is Provided.
Oct-12-2020 13:30:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment

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Subject Initials: ---

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				discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify.
Oct-12-2020 13:30:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Incorrect Query
Oct-12-2020 13:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As per Adverse Event form, AE was the reason for discontinued from the study. However DISPOSITION - TREATMENT and DISPOSITION - FOLLOW-UP do not have the Status updated as Adverse Event. Please review and update as appropriate.
Sep-28-2020 17:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry : PREGNANCY	Initial Entry

4. Specify Status:

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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: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-12-2020 15:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-12-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: THAT IS BECA USE THE TREA TMENT DISCO NTINUATION F ORM HAS AN O PTION OF "PRE GNANCY."	Initial Entry

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Header Text: c4591001

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Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EXPOSURE DURING PREGNANCY	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561015**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Nov-12-2020 16:15:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Closed	Response satisfies query
Nov-12-2020 09:31:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 2 : Answered	IN V1 VISIT, A PREGNANCY TEST WAS PERFORMED AND RESULTS WERE NEGATIVE. IT HAS BEEN DOCUMENTED IN V1
Nov-12-2020 04:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2 : Opened	As per completion guidelines version 10.0, If conception occurred prior to vaccination 1, time to be recorded as UNK:UNK. Please review and update as appropriate. Else clarify.
Nov-11-2020 17:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1 : Deleted	New Information
Nov-11-2020 17:36:29 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/21/ 2020 12: 25	New Information

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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Canada)				
Nov-10-2020 02:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Reissued: Candidate	For Clinical review
Nov-09-2020 14:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	I AM NOT QUITE SURE THAT WE UNDERSTAND YOUR REQUEST. WE DO NOT HAVE AN EDP GUIDANCE DOCUMENT TO REFERENCE. THE LMP IS NOT NECESSARILY THE DATE OF CONCEPTION, AND IT IS NOT POSSIBLE TO KNOW IF THE SUBJECT WAS INDEED PREGNANT AT DOSE 1.
Nov-06-2020 07:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Opened	SAE RECON:AER#2020377626, the onset date was reported as 28Sep2020 in both database. However,based on EDP guidance,the date of onset = Vax1 = 21Aug2020. The participant was pregnant at enrollment LMP = 04Aug2020. Please confirm and update both

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				database.
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/28/ 2020 12 :25	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-30-2020 14:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Ok. Thank you.
Oct-30-2020 12:13:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PLEASE HAVE SOMEONE PROVIDE GUIDANCE ON HOW THEY WOULD LIKE THE INTENSITY OF AN EVENT THAT IS

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Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

				NOT AN ADVERSE EVENTS TO BE DETERMINED. WHEN THIS GUIDANCE IS RECEIVED WE WILL GO AHEAD AND UPDATE.
Oct-29-2020 18:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Appreciate the response. Kindly revise the following options stated in the CRF CG section 8.50.5: Grace 1 = MILD Grade 2 = MODERATE Grade 3 = SEVERE Grade 4 = LIFE-THREATENING Thank you.
Oct-28-2020 18:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	"EDP DID NOT HAVE AN ASSOCIATED AE. PER SAE FORM JOB AID, CERTAIN INFO SHOULD BE LEFT BLANK; I.E., SERIOUSNESS CRITERIA, STATUS AT LAST OBSERVATION."
Oct-28-2020 16:53:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Kindly revise CRF completion guidelines section 8.50.5. Toxicity Grade. Please consider/review intensity grades defined in the

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				table. Thank you.
Oct-17-2020 16:21:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EDP DID NOT HAVE AN ASSOCIATED AE, THERE IS NOT TOXICITY/INTENSITY TO PROVIDE. PER SAE FORM JOB AID, CERTAIN INFO SHOULD BE LEFT BLANK; I.E., SERIOUSNESS CRITERIA, STATUS AT LAST OBSERVATION.
Oct-13-2020 22:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Information on the toxicity grade should be provided. Please review and update grading accordingly.
Oct-05-2020 13:32:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	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**

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

Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-30-2020 14:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Puig (b) (4)	Query 2: Closed	Response satisfies query
Oct-30-2020 12:14:49 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

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Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)				
Oct-30-2020 12:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> THERE IS NOT AN UNDERLYING CAUSE. THIS EVENT IS A STANDARD PREGNANCY.	Changed Information
Oct-30-2020 03:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: The response for "Is this event related to study treatment" Is reported as 'Not Related', however response for, 'Please indicate

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Subject Initials: ---

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				what this event is due to' is missing. Kindly review and update.
Oct-29-2020 14:09:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thank you.
Oct-28-2020 18:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-28-2020 18:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry
Oct-28-2020 18:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-28-2020 16:47:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Kindly, re-assess if this adverse event is related to study treatment and record NOT

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				RELATED or RELATED. Thank you.
Oct-17-2020 16:20:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EDP DID NOT HAVE AN ASSOCIATED AE. PER SAE FORM JOB AID, CERTAIN INFO SHOULD BE LEFT BLANK; I.E., SERIOUSNESS CRITERIA, STATUS AT LAST OBSERVATION. ARE YOU STATING THAT CAUSALITY MUST BE ASSESSED?
Oct-13-2020 22:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per section 8.47.8. of CRF completion guidelines: "Assess if this adverse event is related to study treatment and record NOT RELATED or RELATED".

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Generated By: (b) (4)

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				Please review and update this field accordingly. Thank you
Oct-05-2020 13:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:26:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Moving Query to EOT form.
Oct-09-2020 15:16:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	CAN YOU PLEASE CLARIFY YOUR REQUEST? THE SUBJECT HAS ALREADY HAD THEIR EOT FORM COMPLETED.
Oct-09-2020 04:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly update adverse event on end of treatment on status. Else clarify. Thank

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Subject Initials: ---

Generated By: (b) (4)

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				you.
Oct-08-2020 17:19:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	THE SUBJECT IS DISCONTINUED FROM IP DUE TO AE, HOWEVER, THE SUBJECT CONTINUES FOR FOLLOW-UP IN THE STUDY
Oct-08-2020 09:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify.
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

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Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 07:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-12-2020 02:10:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Related query present
Nov-11-2020 18:44:31	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	NOT APP

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Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Nov-11-2020 18:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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-11-2020 18:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Changed Information
Nov-11-2020 17:37:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Nov-11-2020 17:37:27 (UTC-05:00)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NOT RECOVERED/NOT RES	Initial Entry

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Generated By: (b) (4)

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Eastern Time
(US & Canada)

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

Date	Location	User	Value	Reason
Nov-11-2020 17:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry :	Initial Entry
Nov-11-2020 06:04:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020377626, the outcome in AE CRF was reported as Not Applicable. Based on the latest EDP guidance, outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Oct-30-2020 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thank you.
Oct-30-2020 12:11:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	"EDP DID NOT HAVE AN ASSOCIATED AE. PER SAE FORM JOB AID, CERTAIN INFO SHOULD BE LEFT BLANK; I.E., SERIOUSNESS CRITERIA,

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

				STATUS AT LAST OBSERVATION."
Oct-29-2020 18:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Appreciate the response. Kindly choose between the following options stated in the CRF CG: FATAL NOT RECOVERED/NOT RESOLVED RECOVERED/RESOLVED RECOVERED/RESOLVED WITH SEQUELAE RECOVERING/RESOLVING UNKNOWN Thank you.
Oct-28-2020 18:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	"EDP DID NOT HAVE AN ASSOCIATED AE. PER SAE FORM JOB AID, CERTAIN INFO SHOULD BE LEFT BLANK; I.E., SERIOUSNESS CRITERIA, STATUS AT LAST OBSERVATION."
Oct-28-2020 16:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Kindly review the CRF completion guidelines section 8.50.12. "What was the outcome of this adverse event?" so this row is recorded accordingly. Thank you.
Oct-17-2020 16:21:10 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EDP DID NOT HAVE AN ASSOCIATED AE. PER SAE FORM JOB AID, CERTAIN

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (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:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561015**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Eastern Time (US & Canada)			d	INFO SHOULD BE LEFT BLANK; I.E., SERIOUSNESS CRITERIA, STATUS AT LAST OBSERVATION.
Oct-13-2020 22:11:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Op ened	Clinical_Per section 8.47.12. of CRF completion guidelines: "Record the appropriate outcome of the event in relation to the Participant's status". Please review and update this field accordingly. Thank you
Oct-05-2020 13:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 13:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

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

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-18-2021 17:08:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Feb/18/2021	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

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

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Feb-18-2021 17:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 17:08:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-18-2021 17:08:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Participant is willin g to return for Vacc ination 3 Participant is: eligible per loca l/national recom mendations and confirmed to ha	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

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

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

Site No: 1156 **Site Name:** (1156) Acevedo Clinical Research Associates

Subject No: 11561015 **Subject Initials:** ---

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

			ve received only placebo at Vacci nation 1/2	
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-18-2021 17:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Feb/18/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-18-2021 17:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Sep-28-2020 17:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Aug-21-2020 17:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-21-2020 17:05:57 (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
Sep-28-2020 17:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/28/2020	Initial Entry
Aug-21-2020 17:08:45	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561015

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)				
Aug-21-2020 17:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561015

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-15-2020 11:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30c6\Final\Final On: 01-Apr-2021 04:16 (GMT)