

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: 11561007

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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/20/2020
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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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11561007]
2.	Birth Date:	(b) (6)/1998
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:	

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

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/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1156

Subject No: 11561007

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561007

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/20/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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:	[Obesity]
	Start Date:	Jun/6/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Menorrhagia]
	Start Date:	Jan/3/2020
	Ongoing:	NO End Date: Jan/20/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[C-section]
	Start Date:	May/16/2019
	Ongoing:	NO End Date: May/16/2019

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1156

Subject No: 11561007

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

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](#)

Vital Signs

1.	Date:	Aug/20/2020
2.	Weight:	[83.6]
3.	Unit:	kg
4.	Height:	[160.3]
5.	Unit:	cm
6.	Body Mass Index:	[32.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[96.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1156

Subject No: 11561007

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/20/2020
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:	

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561007

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/20/2020
2.	Randomization Number:	[58521]
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: 11561007

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/20/2020
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	[BP184F]
5.b	Sample ID	[BP184G]
5.c	Sample ID	[BP184H]
5.d	Sample ID	[BPHRX8]
5.e	Sample ID	[BPHRX9]

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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/20/2020
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	[BP184D]
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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561007

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/20/2020 15:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1156

Subject No: 11561007

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: 11561007

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/10/2020
2.	Erroneous Visit	

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/10/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1156

Subject No: 11561007

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/10/2020
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:	

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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/10/2020
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	[BP18JW]
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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561007

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:	Sep/10/2020 16:04
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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

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

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

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

Subject No: 11561007 **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/12/2020
2.	Erroneous Visit	

Header Text: c4591001

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

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

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

Subject No: 11561007 **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/12/2020
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	[BPHRP7]
5.b	Sample ID	[BPHRP8]
5.c	Sample ID	[BR2Z19]

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

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: 11561007

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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

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: 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: 11561007

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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

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: 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: 11561007

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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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: 11561007

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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?	
----	--	--

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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: 11561007

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: 11561007

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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007 **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: 11561007 **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: 11561007 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

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:	[]

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

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: 11561007

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: 11561007 **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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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	HEMOPTYSIS	Oct/4/2020 UNK:UNK	NO End Date Time: Oct/4/2020 UN K:UNK	Repeating Pages
2.	ADVERSE EVENT	2	INCOMPLETE SPONTANEOUS ABORTION	Oct/4/2020 UNK:UNK	NO End Date Time: Oct/7/2020 UN K:UNK	Repeating Pages

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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: [UNKNOWN ETIOLOGY]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
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: [UNKNOWN ETIOLOGY]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020389575]

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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: 11561007

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	[]

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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: 11561007

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:	//

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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: 11561007

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

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: 11561007

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:	

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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:	

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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?	

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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: 11561007

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: 11561007 **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: 11561007

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: 11561007

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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

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: 11561007

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	Mar/1/2021
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: 11561007

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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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: 11561007

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: 11561007

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: 11561007

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: 11561007

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: 11561007

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:	[]

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/12/2020

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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

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	Mar-02-2021 15:11:31 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 16:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	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: 11561007

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	Mar-02-2021 15:11:31 (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	Mar-01-2021 14:55:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
----------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Hector Rodriguez	Approved	Nov-03-2020 14:15:47 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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.

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-20-2020 16:41:50 (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-20-2020 16:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: STAGE 3 COHORT S	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-20-2020 16:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Aug/20/2020	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1156

Subject No: 11561007

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-20-2020 16:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11561007	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-09-2020 06:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 18:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THE SAE FORM SUBMITTED ON 07-OCT-2020 IS NOT MISSING ANY OF THE INFORMATION THAT YOU'RE SUGGESTING. I HAVE REVIEW AND CONFIRMED THAT ALL REQUIRE INFORMATION WAS ENTERED.
Oct-08-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1:	SAE

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

06:41:15 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Opened	RECON:AER#2020389575 ,the date of birth was missing in Safety database but was recorded as (b) (6) /1998in AE CRF.Please confirm if date of birth was reported.If safety update is required, please submit a follow-up form
Aug-20-2020 16:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1 998	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-09-2020 06:08:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 18:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THE GENDER WAS SELECTED AS FEMALE ON PAGE 1 OF VACCINE SAE REPORTING FORM INITIAL SUBMITTED 07-OCT-2020.
Oct-08-2020 06:42:33	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020389575

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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)		,the gender was missing in Safety database but was recorded as FEMALE in AE CRF.Please confirm if gender was reported.If safety update is required, please submit a follow-up form
Aug-20-2020 16:42:12 (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-20-2020 16:42:12 (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):

Date	Location	User	Value	Reason
Aug-20-2020 16:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BLACK OR AFRICAN AMERICAN	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

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-20-2020 16:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561007

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-20-2020 16:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-20-2020 16:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-20-2020 16:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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1.a

Date	Location	User	Value	Reason
Aug-20-2020 16:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Obesity Start Date: Jun/6/2019 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-20-2020 16:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 16:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Obesity	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

1.a Start Date:

Date	Location	User	Value	Reason
Aug-20-2020 16:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Jun/6/2019	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-20-2020 16:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-20-2020 16:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His Menorrh tory Term: agia Start Date: Jan/3/20 20	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561007

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Ongoing: NO	
			End Date:	
			Jan/20/2020	

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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-20-2020 16:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 16:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Menorrhagia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-20-2020 16:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Jan/3/2020	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-20-2020 16:44:38	ACV0PFEINFP6000	Hector Aguilar	Data Entry: NO	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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

(b) (4)

End Date:

Jan/20/2020

I.c

Date	Location	User	Value	Reason
Aug-20-2020 16:45:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical Hi C-section story Term : Start Date: May/16/2 019 Ongoing: NO End Dat e: May/1 6/2019	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-20-2020 16:45:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 16:45:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: C-section	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-20-2020 16:45:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: May/16/2019	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-20-2020 16:45:19	ACV0PFEINFP6000	Hector Aguilar	Data Entry: NO	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	End Date: May/16/2019	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

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-20-2020 16:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/20/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 83.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:01 (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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Aug-20-2020 16:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 160.3	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:01 (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-20-2020 16:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-20-2020 16:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Record Identifier: Temperature: 96.6	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

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-20-2020 16:46:01 (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-24-2020 07:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site's confirmation.
Aug-21-2020 09:19:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	not clinically significant
Aug-21-2020 06:48:52 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Confirmation on the out of

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				range value as clinically significant or not is expected. Please review and confirm.
Aug-20-2020 17:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	Original value is correct
Aug-20-2020 16:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.6 F is outside of Normal Range 97 - 99.5 F.
Aug-20-2020 16:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 96.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: F	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:01 (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: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

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
Aug-20-2020 16:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/20/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Aug-20-2020 16:46:11 (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-20-2020 16:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-20-2020 16:46:11 (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:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-20-2020 16:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:11 (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-20-2020 16:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561007

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-20-2020 16:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/20/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-20-2020 16:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 58521	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561007

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-20-2020 16:46:47 (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-20-2020 16:46:47 (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-20-2020 16:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 16:46:47 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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-20-2020 16:46:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 16:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP184 : F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP184F	Initial Entry

5.b

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-20-2020 16:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP184 : G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP184G	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-20-2020 16:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP184 : H	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP184H	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-20-2020 16:47:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample I BPHRX D: 8	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:47:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BPHRX8	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-20-2020 16:47:52	ACV0PFEINFP6000	Hector Aguilar	Data Entry: Sample I BPHRX	Initial Entry

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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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	D: 9	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BPHRX9	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561007

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-20-2020 16:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-20-2020 16:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-20-2020 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 16:49:24 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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-20-2020 16:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP184 : D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP184D	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561007

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-20-2020 16:50:52 (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-20-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-20-2020 16:50:52 (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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Aug-20-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Aug/20/2020 15:26	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-20-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-20-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-20-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561007

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-20-2020 16:50:52 (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-20-2020 16:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1156

Subject No: 11561007

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 10:09:41 (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-20-2020 16:51:02 (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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561007

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-10-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1156

Subject No: 11561007

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-10-2020 16:19:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 16:19:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 16:19:16 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 1	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 16:19:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 98.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 16:19:16 (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-10-2020 16:19:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

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-10-2020 16:19:33 (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
Sep-10-2020 16:19:33 (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-10-2020 16:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Sep-10-2020 16:19:33 (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
Sep-10-2020 16:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 16:19:33 (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:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-10-2020 16:19:33 (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-10-2020 16:19:33 (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
Sep-10-2020 16:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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-10-2020 16:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 16:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 16:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 16:47:02 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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-10-2020 16:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 16:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP18J : W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 16:47:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP18JW	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561007

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-10-2020 16:20:14 (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
Sep-10-2020 16:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 16:20:14 (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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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Sep-10-2020 16:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/10/2020 16:04	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 16:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 16:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 16:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 16:20:14 (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
Sep-10-2020 16:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

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: 11561007

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-12-2020 17:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Oct/12/2020	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007 **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-12-2020 18:38:57 (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-12-2020 18:38:57 (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-12-2020 18:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 18:38:57 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007 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-12-2020 18:38:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 18:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BPHRP : 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 18:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BPHRP7	Initial Entry

5.b

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-12-2020 18:39:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BPHRP : 8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 18:39:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BPHRP8	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 18:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BR2Z1 : 9	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 18:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BR2Z19	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: 11561007

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
Oct-12-2020 17:01:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Oct/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-12-2020 17:01:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-12-2020 17:01:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 16:54:35 (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-07-2020 16:54:35 (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-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEMOPTYSIS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Oct-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/4/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/4/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-09-2020 10:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Oct-08-2020 18:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS IS A TRANSCRIPTION OF THE PI'S ASSESSMENT OF SERIOUSNESS CRITERIA.
Oct-08-2020 14:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please provide PI's assessment on if it was a medically important event. If yes, a SAE report is required. If it is considered related to the SAE of abortion, e.g., same underlying cause, it can be added as the 2nd term for the same SAE report.
Oct-07-2020 16:54:35 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

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-07-2020 16:54:35 (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-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to s tudy treatment(s), this event is due to : OTHER If Other, specify : UNKNOWN ETIOLOGY	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Oct-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 16:54:35 (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-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Oct-07-2020 16:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 16:55:55 (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-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-03-2020 12:55:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Cl osed	Answer was send in error. Response satisfy query = yes. Apologies. Thank you.
Dec-03-2020 12:29:57	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 3: An swered	Query is ambiguous

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(UTC-05:00) Eastern Time (US & Canada)				
Dec-03-2020 02:33:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Re issued:Open ed	Response does not satisfy query
Dec-02-2020 18:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Re issued:Cand idate	Response does not satisfy query
Dec-02-2020 10:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 3: An swered	AE OF HEMOPTYSIS HAS ALREADY BEEN ADDED
Dec-01-2020 15:02:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Op ened	The case narrative records that the subject presented to the ER with pelvic pain and "hemoptysis". Please confirm AE of hemoptysis and if so, the subsequent work-up.
Nov-02-2020 12:55:01 (UTC-05:00)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Cl osed	Thank you.

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Subject Initials: ---

Generated By: (b) (4)

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Eastern Time (US & Canada)				
Oct-30-2020 12:10:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	IN PROCESS
Oct-29-2020 18:25:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Re issued: Opened	Appreciate the response. However, this study is assessing the IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY ADULTS. Kindly, record in the SAE report if Covid test was negative/not performed/Unknown. Thanks
Oct-23-2020 12:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE WAS SUBMITTED CORRECTLY USING THE SAE JOB GUIDE PROVIDED BY PFIZER. IF THE SPONSOR

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Subject Initials: ---

Generated By: (b) (4)

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				REQUIRES THE GATHERING OF SPECIFIC INFO, IT SHOULD BE PROVIDED IN A FORMAL DOCUMENT TO AVOID UNNECESSARY WORK FOR SITES.
Oct-22-2020 14:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Re issued: Opened	If test was NOT performed or NOT available, please add this information as well so it is reflected in the SAE case narrative. Thank you.
Oct-21-2020 14:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	IF A COVID-19 TEST WAS DONE, IT WOULD HAVE BEEN ADDED TO THE SAE REPORT.
Oct-21-2020 11:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed during hospitalization (yes/no) and if yes,

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Generated By: (b) (4)

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				the results. Thank you.
Oct-16-2020 10:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 09:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS HAS BEEN REPORTED SEVERAL TIMES
Oct-15-2020 01:56:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: If Exposure During Pregnancy occurs in a subject or subject's partner, the investigator must report this to Pfizer Safety on the Vaccines SAE report Form and an EDP supplemental form. Please confirm the EDP supplemental form was completed.
Oct-14-2020 15:29:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: If Exposure During Pregnancy occurs in a subject or subject's partner, the investigator must

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Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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				report this to Pfizer Safety on the Vaccines SAE report Form and an EDP supplemental form. Please confirm the EDP supplemental form was completed.
Oct-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : INCOMPLETE SPONTANEOUS ABORTION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-04-2020 16:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Dec-03-2020 12:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	SAE REPORT REFERS TO CONCEPTION, BUT THE AE REFERS TO INCOMPLETE SPONTANEOUS ABORTION. THEY ARE TWO

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Subject Initials: ---

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				DIFFERENT THINGS, WITH TWO SEPERATE START DATES.
Dec-02-2020 19:33:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for your response. The SAE report submitted to safety (case narrative) records a date of conception of Aug 2020. Kindly revise and update onset date accordingly. Thank you
Dec-02-2020 11:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	PLEASE ADVISE WHERE IN THE SOURCE IS THE CASE NARRATIVE TO WHICH YOU REFER.
Dec-01-2020 15:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative, the date of conception is Aug 2020. Kindly revise and

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Header Text: c4591001

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Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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				update onset date accordingly. Thank you.
Oct-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/4/2020 UN K:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-09-2020 15:18:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/7/2020 UN K:UNK	New Information
Oct-07-2020 16:55:55 (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-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

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Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-08-2020 06:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE INCOMPLETE SPONTANEOUS ABORTION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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			or birth defect ?	
			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			NO	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medical	

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Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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			y important se rious event	
			YES	

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-07-2020 16:55:55 (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-09-2020 06:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 18:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THE SAE FORM SUBMITTED ON 07-OCT-2020 IS NOT MISSING ANY OF THE INFORMATION THAT YOU'RE SUGGESTING. I HAVE REVIEWED AND CONFIRMED THAT ALL

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Subject Initials: ---

Generated By: (b) (4)

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

				REQUIRED INFORMATION WAS ENTERED. I'M QUITE CONFUSED AS TO WHAT DOCUMENT YOU ARE REFERENCING.
Oct-08-2020 06:44:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020389575 ,the causality was recorded as NO DATA in Safety database but was recorded as NOT RELATED in AE CRF.Please confirm correct causality.If safety update is required, please submit a follow-up form
Oct-07-2020 16:55:55 (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	Initial Entry

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			<p><i>If Other, specify:</i></p> <p>U N K N O W N E T I O L O G Y</p>	
--	--	--	---	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-09-2020 06:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-08-2020 18:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	THE SAE FORM SUBMITTED ON 07-OCT-2020 IS NOT MISSING ANY OF THE INFORMATION THAT YOU'RE SUGGESTING. I

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				HAVE REVIEWED AND CONFIRMED THAT ALL REQUIRED INFORMATION WAS ENTERED. I'M QUITE CONFUSED AS TO WHAT DOCUMENT YOU ARE REFERENCING.
Oct-08-2020 06:46:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020389575 ,the Action taken was missing in Safety database but was recorded as NOT APPLICABLE in AE CRF.Please confirm correct action taken.If safety update is required, please submit a follow-up form
Oct-08-2020 06:45:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	corrected query text
Oct-08-2020 06:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020389575 ,the Action taken was missing in Safety database but was recorded as NOT APPLICABLE in AE CRF.Please confirm correct

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				outcome.If safety update is required, please submit a follow-up form
Oct-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 16:55:55 (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-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
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Oct-12-2020 05:48:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query.
Oct-12-2020 05:14:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-11-2020 17:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Oct-11-2020 17:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-10-2020 08:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Per response "UPDATED"; however data is not updated in 'What was the outcome of this adverse event' or 'End Date' field. Please review the data.

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Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-09-2020 15:19:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Answered	UPDATED
Oct-09-2020 15:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	UPDATED
Oct-09-2020 15:18:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Opened	For AE INCOMPLETE SPONTANEOUS ABORTION: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-09-2020 06:12:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Reissued: Opened	SAE RECON 1: Outcome was updated in Safety database to RECOVERED/RESOLVED but retained as NOT RECOVERED/NOT RESOLVED in AE

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Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

				CRF.Please confirm correct outcome.If safety update is required, please submit a follow-up form
Oct-08-2020 18:44:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	OUTCOME WAS UPDATED ON FOLLOW-UP REPORT 1 SUBMITTED 08-OCT-2020
Oct-08-2020 06:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Opened	SAE RECON:AER#2020389575 ,the outcome was missing in Safety database but was recorded as OT RECOVERED/NOT RESOLVED in AE CRF.Please confirm correct outcome.If safety update is required, please submit a follow-up form
Oct-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Initial Entry

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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-07-2020 16:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-08-2020 06:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020389575	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

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

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

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

Subject No: 11561007 **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
Mar-01-2021 14:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Mar/1/2021	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007 **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
Mar-01-2021 14:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 14:55:50 (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.
Mar-01-2021 14:55:50 (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

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007 **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: 11561007

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
Mar-01-2021 14:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Mar/1/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-01-2021 14:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

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
Oct-12-2020 17:01:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-20-2020 16:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-20-2020 16:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-12-2020 17:01:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/12/2020	Initial Entry
Aug-20-2020 16:46:32	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (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: 11561007

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)				
Aug-20-2020 16:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561007

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-03-2020 14:08:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30c4\Final\Final On: 01-Apr-2021 04:15 (GMT)