

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: 11561131

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

090177e196ae30bb\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: 11561131

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 Sep/11/2020
----	--------------	--

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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11561131]
2.	Birth Date:	(b) (6)/1974
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_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: 11561131

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/11/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1156

Subject No: 11561131

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

090177e196ae30bb\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: 11561131

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	Sep/11/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[complex injury of left hand]
	Start Date:	Sep/17/2016
	Ongoing:	NO End Date: Sep/17/2016
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[reconstruction of forearm wound with fasciocutaneous flap]
	Start Date:	Sep/17/2016
	Ongoing:	NO End Date: Sep/17/2016

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/11/2020
2.	Weight:	[75.6]
3.	Unit:	kg
4.	Height:	[176.78]
5.	Unit:	cm
6.	Body Mass Index:	[24.2]

Vital Signs Details

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

090177e196ae30bb\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: 11561131

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 :	Sep/11/2020
2.	Randomization Number:	[86980]
3.	Randomization Group:	[]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

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: 11561131

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: Sep/11/2020
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	[BP18JZ]
5.b	Sample ID	[BPHS59]
5.c	Sample ID	[BPHS5B]

090177e196ae30bb\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: 11561131

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/11/2020
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	[BP18K7]
-----	-----------	----------

090177e196ae30bb\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: 11561131

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/11/2020 11:25
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

090177e196ae30bb\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: 11561131

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
----	---	---

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

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: 11561131

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/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

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:	Sep/30/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30bb\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: 11561131

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/30/2020
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	[BP18V2]
-----	-----------	----------

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/30/2020 16:10
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

090177e196ae30bb\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: 11561131 **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/30/2020
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: 11561131 **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/30/2020
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	[BR69S2]
5.b	Sample ID	[BRZPW3]
5.c	Sample ID	[BRZPW4]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: DATE OF VISIT - ILLNESS ONSET

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: 11561131

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	Dec/29/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 10-Dec-2020 02:29

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/29/2020
2.	Date of First Symptom Started:	Dec/28/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/1/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	YES
Symptoms - Other		
5.	Symptoms - Other Text:	[]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Applicable _____ //	Comments
2.	Specimen Type:	Not Applicable _____	Comments
3.	Specimen Collection Location:	Not Applicable _____	Comments
4.	Assay Code and Description:	Not Applicable _____	Comments
5.	Device Type:	Not Applicable _____	Comments
6.	Trade Name:	Not Applicable _____	Comments
7.	Test Result:	Not Applicable _____	Comments
8.	Comments/Findings /Details:	Not Applicable _____ []	Comments
9.	Trade Name Other, Specify:	Not Applicable _____ []	Comments

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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: Dec/29/2020
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	[BR3NGV]
-----	-----------	----------

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Respiratory Treatment

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

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

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: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/26/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

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	Jan/26/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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: Jan/26/2021
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	[BR38V3]
5.b	Sample ID	[BS60GD]
5.c	Sample ID	[BS60GC]

090177e196ae30bb\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: 11561131 **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: 11561131 **Subject Initials:** ---

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

Unplanned Assessments

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

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

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

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

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

Subject No: 11561131 **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/30/2020
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: 11561131

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:	[]

090177e196ae30bb\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: 11561131

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: 11561131 **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	[]
----	-----------	-----

090177e196ae30bb\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: 11561131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Adverse Event Report

1.	Category:	
2.	AE ID:	[]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	

090177e196ae30bb\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: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae30bb\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: 11561131

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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Medication Error

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

090177e196ae30bb\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: 11561131

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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae30bb\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: 11561131

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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae30bb\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: 11561131

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

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: 11561131

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?	

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

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: 11561131

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: 11561131

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:	

090177e196ae30bb\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: 11561131

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?	

090177e196ae30bb\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: 11561131

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: 11561131

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: 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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/22/2021
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: 11561131 **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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae30bb\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: 11561131

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: 11561131

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:	[]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/25/2021
----	--------------	--

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Feb/25/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 11561131

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: Feb/25/2021
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	[BRLYB2]
5.b	Sample ID	[BS2F7B]
5.c	Sample ID	[BS2F79]

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 11561131

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: Feb/25/2021
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	[BRLYBL]
-----	-----------	----------

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/25/2021 15:58
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 11561131

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

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 11561131

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?	

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

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: 11561131

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561131

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561131

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

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: 11561131

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/30/2020

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: 11561131

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: 11561131

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-04-2021 12:13:17 (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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-11-2020 14:27:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
6	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
7	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
8	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
9	Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-25-2021 17:41:28 (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: 11561131

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-04-2021 12:13:17 (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	Jan-26-2021 16:28:03 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
----------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Hector Rodriguez	Approved	Jan-23-2021 14:20:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

090177e196ae30bb\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: 11561131

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.

Hector Aguilar	N/A	Dec-30-2020 09:41:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
----------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Hector Rodriguez	Approved	Nov-04-2020 14:35:54 (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.

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-11-2020 14:26:23 (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
Sep-11-2020 14:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-11-2020 14:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Sep/11/2020	Initial Entry

090177e196ae30bb\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: 11561131

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-11-2020 14:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11561131	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1974	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-11-2020 14:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Sep-11-2020 14:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: HISPANIC OR LATI NO(A) OR OF SPA NISH ORIGIN	Initial Entry
---	-----------------	------------------------------	--	---------------

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

Date	Location	User	Value	Reason
Sep-11-2020 14:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BLACK OR AFRIC AN AMERICAN	Initial Entry

090177e196ae30bb\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: 11561131

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-11-2020 14:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/11/2020	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-11-2020 14:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-11-2020 14:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-11-2020 14:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Sep-11-2020 14:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical History Term: complex injury of left h and Start Date: Sep/17/2016 Ongoing: NO End Date: Sep/17/2016	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:04 (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
------	----------	------	-------	--------

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Sep-11-2020 14:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: complex injury of left hand	Initial Entry
--	-----------------	---------------------------	---	---------------

1.a Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/17/2016	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO End Date: Sep/17/2016	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-11-2020 14:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/ 2 MH N umber:	Initial Entry

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Medic reconstruction al His of forearm wou tory T nd with fascioc erm: utaneous flap Start Sep/17/2016 Date: Ongoi NO ng: End Date: Sep/17/201 6</p>	
--	--	--	--	--

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:31:36 (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
Sep-11-2020 14:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: reconstruction of fore arm wound with fasc iocutaneous flap	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/17/2016	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:31:36	ACV0PFEINFP6000	Hector Aguilar	Data Entry: NO	Initial Entry

090177e196ae30bb\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: 11561131

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:

Sep/17/2016

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/11/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 75.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30bb\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: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 176.78	Initial Entry
--	-----------------	---------------------------	------------------------------	---------------

5. Unit:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:44 (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
Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Record Identifier: Temperature: 97.3	Initial Entry

090177e196ae30bb\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: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

			Temperature Unit: Temperature Location: ORAL CAVITY Y
--	--	--	--

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:44 (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
Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 97.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: F	Initial Entry

090177e196ae30bb\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: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30bb\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: 11561131

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-11-2020 14:33:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/11/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:33:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 86980	Initial Entry

090177e196ae30bb\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: 11561131

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-11-2020 17:42:05 (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-11-2020 17:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-11-2020 17:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 17:42:05 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30bb\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: 11561131

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-11-2020 17:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 17:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP18J : Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 17:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP18JZ	Initial Entry

5.b

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-11-2020 17:42:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BPHS5 : 9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 17:42:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BPHS59	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-11-2020 17:43:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BPHS5 : B	Initial Entry

090177e196ae30bb\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: 11561131

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

5.c Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 17:43:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BPHS5B	Initial Entry

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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-11-2020 17:43:07 (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-11-2020 17:43:07 (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-11-2020 17:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 17:43:07 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30bb\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: 11561131

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-11-2020 17:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 17:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP18K : 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 17:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP18K7	Initial Entry

090177e196ae30bb\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: 11561131

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-11-2020 14:33:42 (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-11-2020 14:33:42 (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-11-2020 14:33:42 (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
------	----------	------	-------	--------

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Sep-11-2020 14:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/11/2020 11:25	Initial Entry
---	-----------------	------------------------------	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-11-2020 14:33:42 (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-11-2020 14:33:42 (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-11-2020 14:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30bb\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: 11561131

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
Sep-11-2020 14:33:42 (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-11-2020 14:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30bb\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: 11561131

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-11-2020 14:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

090177e196ae30bb\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: 11561131

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 18:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/30/2020	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1156

Subject No: 11561131

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-30-2020 18:38:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/30/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-30-2020 18:38:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Record Identifier:: Temperature: 98.3 Temperature Unit: Temperature Location: ORAL Temperature Unit: CAVIT Temperature Unit: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-30-2020 18:38:45 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 1	Initial Entry

090177e196ae30bb\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: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-30-2020 18:38:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-30-2020 18:38:45 (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-30-2020 18:38:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-30-2020 18:44:42 (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-30-2020 18:44:42 (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-30-2020 18:44:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 18:44:42 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30bb\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: 11561131

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-30-2020 18:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-30-2020 18:44:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BP18V : 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 18:44:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BP18V2	Initial Entry

090177e196ae30bb\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: 11561131

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-30-2020 18:39:19 (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-30-2020 18:39:19 (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-30-2020 18:39:19 (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
------	----------	------	-------	--------

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Sep-30-2020 18:39:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sep/30/2020 16:10	Initial Entry
---	-----------------	------------------------------	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-30-2020 18:39:19 (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-30-2020 18:39:19 (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-30-2020 18:39:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30bb\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: 11561131

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-30-2020 18:39:19 (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-30-2020 18:39:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30bb\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: 11561131 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-30-2020 16:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Oct/30/2020	Initial Entry

090177e196ae30bb\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: 11561131 **Subject Initials:** ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 17:50:25 (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-30-2020 17:50:25 (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-30-2020 17:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 17:50:25 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30bb\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: 11561131 **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-30-2020 17:50:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Oct/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 17:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BR69S : 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 17:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BR69S2	Initial Entry

5.b

090177e196ae30bb\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: 11561131 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-30-2020 17:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample I BRZPW D: 3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 17:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BRZPW3	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 17:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample I BRZPW D: 4	Initial Entry

090177e196ae30bb\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: 11561131 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 17:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BRZPW4	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-30-2020 09:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-30-2020 09:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-30-2020 09:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: DATE OF VISIT - ILLNESS ONSET - 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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-30-2020 09:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Dec/29/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-30-2020 09:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 10-Dec-2020 02:29

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Dec/29/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Dec/28/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 15:11:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO Date of Last Symptom Resolved: Jan/1/2021	New Information
Dec-30-2020 09:42:29	ACV0PFEINFP6000	Hector Aguilar	Data Entry: YES	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

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

(b) (4)

4.a

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Symptoms: FEV ER Symptom Pr NO esent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

4.b

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt YES om Pre sent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NEW OR INCREAS ED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-30-2020	ACV0PFEINFP6000	Hector	Data Entry:	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

09:42:29 (UTC-05:00) Eastern Time (US & Canada)		Aguilar (b) (4)	Symp NEW OR IN toms: CREASED S HORTNESS OF BREATH Symp NO tom Prese nt:	
--	--	--------------------	--	--

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NEW OR INCREAS ED SHORTNESS O F BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29	ACV0PFEINFP6000	Hector Aguilar	Data Entry: Symptoms: CHIL	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	LS	
			Symptom Present:	NO

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

			Sympt NO om Pr esent:	
--	--	--	--------------------------------------	--

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NEW OR INCREAS ED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL Sympt NO om Pr esent:	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NEW LOSS OF TAS TE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Symp NEW OR IN toms: CREASED SORE THR OAT Symp NO tom P resent :	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Symptoms DIARR : HEA Symptom NO Present:	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Symptoms VOMI : TING Symptom YES Present:	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 10-Dec-2020 02:29

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 09:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 06-Jul-2020 21:54

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry
---	-----------------	------------------------------	--------------------------------------	---------------

5. Device Type:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-30-2020 09:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-30-2020 09:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 09:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 09:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

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

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Date	Location	User	Value	Reason
Dec-30-2020 09:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: SWAB PFE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-30-2020 09:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 09:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 09:53:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 09:43:17 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - 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: 11561131

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.
Dec-30-2020 09:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Dec/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-30-2020 09:53:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample I BR3NG D: V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 09:53:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BR3NGV	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 10-Dec-2020 02:26

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Type of Prac SPEC titioner: IALI ST Occurrence NO of Visits or C ontacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

1.b

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Type of Pr EMER actitioner: GENC Y ROO M Occurrence NO of Visits or Contact s:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

1.c

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN Occurren NO ce of Visi ts or Con tacts:	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
---	-----------------	------------------------------	---	---------------

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Type of Practitioner: TELEPHONE CONSULT	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)			r: NSULTA TION	
			Occurren NO ce of Visi ts or Con tacts:	

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: TELEPHONE CON SULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Type of Practi OT tioner: HE R	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)			Occurrence of NO Visits or Contacts:	
-----------	--	--	---	--

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Dec-30-2020 09:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-30-2020 09:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 1	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form Version: 17-Jul-2020 21:55

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Dec/29/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Jan-08-2021 15:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Not Applicable	Initial Entry
---	-----------------	------------------------------	--------------------------------------	---------------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/26/2021

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-26-2021 16:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Jan/26/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-26-2021 16:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-26-2021 16:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 16:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-27-2021 11:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 16:29:00 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/26/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1156**Subject No:** 11561131**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-26-2021 16:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Jan/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-27-2021 11:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BR38V : 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 11:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BR38V3	Initial Entry

5.b

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-27-2021 11:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BS60G : D	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 11:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BS60GD	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-27-2021 11:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BS60G : C	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 11:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BS60GC	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: 11561131 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-30-2020 16:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Oct/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-30-2020 16:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-30-2020 16:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30bb\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: 11561131 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 12:32:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Feb/22/2021	Initial Entry

090177e196ae30bb\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: 11561131 **Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-23-2021 12:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 12:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-23-2021 12:32:20 (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

090177e196ae30bb\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: 11561131 **Subject Initials:** ---

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

			ve received only placebo at Vacci nation 1/2	
--	--	--	--	--

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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-23-2021 12:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Feb/22/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-23-2021 12:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 17:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Feb/25/2021	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Feb-25-2021 17:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Feb/25/2021	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-25-2021 17:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Feb/25/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-25-2021 17:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-25-2021 17:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-25-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-26-2021 11:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-26-2021 06:08:25 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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:** 11561131**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.
Feb-25-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 11:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BRLYB : 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Feb-26-2021 11:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BRLYB2	Initial Entry
--	-----------------	---------------------------	------------------------------	---------------

5.b

Date	Location	User	Value	Reason
Feb-26-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BS2F7 : B	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BS2F7B	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-26-2021 11:46:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample ID BS2F7 : 9	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 11:46:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BS2F79	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-25-2021 17:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 17:42:03 (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
Feb-26-2021 11:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-26-2021 06:08:25 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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:** 11561131**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.
Feb-25-2021 17:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 17:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: YES Date of Collection : Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 11:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Sample I BRLYB D: L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Feb-26-2021 11:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: BRLYBL	Initial Entry
---	-----------------	------------------------------	------------------------------	---------------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1156

Subject No: 11561131

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-25-2021 17:42:24 (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
Feb-25-2021 17:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-25-2021 17:42:24 (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
------	----------	------	-------	--------

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

Feb-25-2021 17:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Feb/25/2021 15:58	Initial Entry
---	-----------------	------------------------------	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-25-2021 17:42:24 (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
Feb-25-2021 17:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-25-2021 17:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-25-2021 17:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-25-2021 17:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-25-2021 17:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 17:42:24	ACV0PFEINFP6000	Hector Aguilar	Data Entry: YES	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

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

(b) (4)

Header Text: c4591001

Visit: 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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-30-2020 16:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-11-2020 14:33:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-11-2020 14:27:35 (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-30-2020 16:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/30/2020	Initial Entry
Sep-11-2020 14:33:13	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/11/2020	Initial Entry

090177e196ae30bb\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: 11561131

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)				
Sep-11-2020 14:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/11/2020	Initial Entry

090177e196ae30bb\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: 11561131

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-03-2020 14:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30bb\Final\Final On: 01-Apr-2021 04:15 (GMT)