

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[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	01 DEC 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/7/2021
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11561357]
2.	Birth Date:	(b) (6) 2008
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/7/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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**Exclusion Criteria Met**

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

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Jan/7/2021
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:** 11561357

**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):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[REFRACTIVE AMBLYOPIA (RIGHT EYE)]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[PREMENARCHAL]
	Start Date:	(b) (6) 2008
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** HIV STATUS

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jan/7/2021
2.	Weight:	[40.95]
3.	Unit:	kg
4.	Height:	[160.5]
5.	Unit:	cm
6.	Body Mass Index:	[15.9]

**Vital Signs Details**

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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1156**Subject No:** 11561357**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Jan/7/2021
2.	Randomization Number:	[26052]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/7/2021
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	[BR3NJV]
5.b	Sample ID	[BS608W]
5.c	Sample ID	[BS608V]

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/7/2021
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	[BR3NK5]
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

**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:	Jan/7/2021 17:03
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

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/27/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jan/27/2021
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**Vital Signs Details**

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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1156**Subject No:** 11561357**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/27/2021
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	[BR38VN]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[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:	Jan/27/2021 16:03
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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[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	[BRLYBC]
5.b	Sample ID	[BS2F7Y]
5.c	Sample ID	[BS2F7X]

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form Version:** 30-Apr-2021 01:47

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**Signs and Symptoms**

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
----	-------------------------------------	-----

**Health Care Utilization**

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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Illness Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11561357    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 10-Nov-2021 20:44

**Unplanned Assessments**

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



**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Vital Signs**

1.	Date:	//
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**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Lab Urinalysis**

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

**Lab Result**

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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**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?	

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/28/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/28/2021
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**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -  
Unscheduled 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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/28/2021
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	[BR38W5]
5.b	Sample ID	[BS60H8]
5.c	Sample ID	[BS60H7]

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/28/2021
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	[BR38WF]
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/09/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
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**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/09/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561357**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
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	[AA11000]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/24/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/24/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/24/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561357**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
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	[AA10955]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/10/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	
COVID-19 Surveillance Visit		
3.	COVID-19 Surveillance Visit:	SSWAB_WEEK6

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/10/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1156**Subject No:** 11561357**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
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	[AA10965]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/24/2021
2.	Erroneous Visit	
COVID-19 Surveillance Visit		
3.	COVID-19 Surveillance Visit:	SSWAB_WEEK8

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Mar/24/2021
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	[AA10954]
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/19/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Apr/19/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK12
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/19/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1156**Subject No:** 11561357**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/19/2021
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	[AA40645]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on May/03/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	May/3/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK14
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on May/03/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561357**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: May/3/2021
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	[AA40190]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/13/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	May/13/2021
2.	Erroneous Visit	
COVID-19 Surveillance Visit		
3.	COVID-19 Surveillance Visit:	SSWAB_WEEK16

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/13/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561357**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: May/13/2021
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	[AA40644]
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**Header Text:** c4591001

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

**Form Version:** 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**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:** 11561357      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	May/13/2021
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:** 11561357      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 10-Nov-2021 20:44

[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:** 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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	APPENDICITIS	Jun/10/2021 UNK:UNK	NO End Date Time:  Jun/10/2021 UNK: UNK	<a href="#">Repeating Pages</a>

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[APPENDICITIS]
4.	Start Date Time:	Jun/10/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jun/10/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? NO</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event YES</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	RELATED
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE
11.	<p>Was a Concomitant Medication given?</p>	YES

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021749538]

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**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Medication Error**

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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Concomitant Medications**

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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Concomitant Medications**

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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Radiation Treatment**

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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**Form Version:** 10-Dec-2020 02:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	May/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Death Details**

1.	Date of Collection / Notification of Death:	//
----	---	----

**Cause of Death**

2.	Cause of Death Status:	
	Cause of Death:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	May/17/2021
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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained May/17/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 28-Mar-2021 02:25

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	May/17/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001**Visit:** V101\_VAX3**Form Version:** 30-Apr-2021 01:41**Site No:** 1156**Subject No:** 11561357**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: May/17/2021
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	[BT9SJ7]
5.b	Sample ID	[BKH913]
5.c	Sample ID	[BKH912]

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: May/17/2021
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	[BT9SJ1]
-----	-----------	----------

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[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:	May/17/2021 17:20
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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jun/7/2021
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** V102\_VAX4**Form Version:** 30-Apr-2021 01:41**Site No:** 1156**Subject No:** 11561357**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V102\_VAX4

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jun/7/2021
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	[BT9SMV]
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**Header Text:** c4591001

**Visit:** V102\_VAX4

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

<b>Vaccination</b>		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jun/7/2021 10:59
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

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jul/6/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jul/6/2021
3.	Comments:	[ ]

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11561357

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** 11561357

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**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:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Jul/6/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/25/2021

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[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	Jul-08-2021 15:28:24 (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:** 10-Oct-2020 16:00

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-08-2021 13:00:46 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
1	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

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

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
2	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
3	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

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**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
4	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

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**Subject No:** 11561357

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
5	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

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

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

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

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**Generated By:** (b) (4)

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Item	Date	User	Comment
6.a	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
1	Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
2	Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
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**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
3	Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

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**Form:** LAB URINALYSIS - PREGNANCY TEST -  
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**Form Version:** 10-Dec-2020 02:23

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
4	Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
5	Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

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**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6.a	Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Jan-28-2021 15:37:18 (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:** 28-Mar-2021 02:25

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	May-18-2021 10:56:11 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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Item	Date	User	Comment
3	May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

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[Back to Form](#)

Item	Date	User	Comment
4	May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
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Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6.a	May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
4	Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6.a	Jun-07-2021 14:56:17 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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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	Jul-08-2021 15:28:24 (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	Jul-07-2021 16:23:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Jun-25-2021 11:43:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Affidavit:**

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

Hector Aguilar	N/A	Jun-25-2021 11:41:20 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Jun-23-2021 12:50:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**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.

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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Hector Aguilar	N/A	Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Jun-08-2021 14:26:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**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	Jun-07-2021 14:55:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	May-18-2021 15:04:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**Affidavit:**

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

Hector Aguilar	N/A	May-18-2021 10:55:48 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	May-15-2021 22:21:28 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**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.

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Hector Aguilar	N/A	May-13-2021 15:04:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
N/A

Hector Rodriguez	Approved	May-10-2021 12:52:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**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	May-07-2021 13:53:04 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
N/A

Hector Rodriguez	Approved	Apr-21-2021 14:22:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**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	Apr-20-2021 16:17:07 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Mar-31-2021 14:27:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**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.

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Hector Aguilar	N/A	Mar-30-2021 15:27:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
N/A

Hector Rodriguez	Approved	Mar-23-2021 23:11:18 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**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.

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Jan-08-2021 12:59:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 12:59:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Consent Was:*

Date	Location	User	Value	Reason
Jan-08-2021 12:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/7/2021	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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**1. Subject ID**

Date	Location	User	Value	Reason
Jan-08-2021 12:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 11561357	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Jan-08-2021 12:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2008	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Jan-08-2021 12:59:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Jan-08-2021 12:59:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NOT HISPANIC OR LATI NO(A) OR OF SPANISH O RIGIN	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-08-2021 12:59:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> WHITE	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-08-2021 13:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Jan-08-2021 13:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-08-2021 13:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-08-2021 13:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Jan-08-2021 13:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical History T</b> REFRACTIVE A MBLYOPIA (RIG erm: HT EYE) <b>Start Date:</b> UNK/UNK/2014 <b>e:</b> <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Jan-08-2021 13:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 13:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> REFRACTIVE AMBLYOPI A (RIGHT EYE)	Initial Entry

*1.a Start Date:*

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-08-2021 13:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Jan-19-2021 15:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Jan-19-2021 12:47:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	Query 1: Answered	SUBJECT IS PREMENARCHAL. DIAGNOSIS HAS BEEN ADDED TO MEDICAL HISTORY.
Jan-15-2021 07:34:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: All females <60 require a pregnancy test unless there is a MH entry confirming not of childbearing potential. Please review why a test was not performed; add an entry to the MH to clarify non-childbearing

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				status per CCG 8.7
Jan-08-2021 13:01:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Jan-19-2021 12:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 2</b> <b>ber:</b> <b>Medical Histo</b> PREMENA <b>ry Term:</b> RCHAL <b>Start Date:</b> (b) (6)/2008 <b>Ongoing:</b> YES	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Jan-19-2021 12:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 12:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> PREMENARCHAL	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Jan-19-2021 12:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> (b) (6) 2008	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Jan-19-2021 12:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-08-2021 13:01:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> The subject is NOT known t o be HIV POSITIVE	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> 40.95	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09	ACV0PF EINFP60	Hector Aguilar	<b>Data Entry:</b> 160.5	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
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**5. Unit:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 15.9	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 98.2 <b>Temperature U F</b> <b>nit:</b> <b>Temperature L ORAL CA</b> <b>ocation::</b> VITY	Initial Entry

**7.a Record Identifier:**

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<u>Data Entry:</u> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<u>Data Entry:</u> 98.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<u>Data Entry:</u> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21	ACV0PF EINFP60	Hector Aguilar	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**6.a Test:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Jan-08-2021 13:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> 26052	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-08-2021 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-08-2021 13:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate.
Jan-08-2021 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/7/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 13:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID: BR3NJV</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 13:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BR3NJV	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-08-2021 13:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID: BS608W</b>	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-08-2021 13:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BS608W	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-08-2021 13:40:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BS608V	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-08-2021 13:40:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BS608V	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 13:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-08-2021 13:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-08-2021 13:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 13:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jan-08-2021 13:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/7/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-08-2021 13:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BR3NK5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-08-2021 13:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BR3NK5	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/7/2021 17:03	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE D OBSERVATION 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
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Jan-08-2021 13:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Jan-08-2021 13:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED F OR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-28-2021 15:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**2.d Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> CHILLS	Initial Entry

**2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G  <b>Were fever or system ic symptoms present on the last day the S ubject Diary was co mpleted?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or system ic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERD MUSCLE PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NEW OR WORSENER M USCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENER JOINT PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

**2.h Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD JOI NT PAIN	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.a

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RES DN ES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

5.b

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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**1. Date:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Record Identifi</b> <b>er::</b> <b>Temperature: 97.3</b> <b>Temperature U F</b> <b>nit:</b> <b>Temperature L ORAL CA</b> <b>ocation:: VITY</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-28-2021 15:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> 97.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18	ACV0PF EINFP60	Hector Aguilar	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sponsor-Define d Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**6.a Test:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Jan-28-2021 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 11:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-29-2021 11:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 11:38:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 11:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jan-29-2021 11:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/27/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 11:38:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BR38VN	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 11:38:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BR38VN	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/27/2021 16:03	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE D OBSERVATION 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
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Jan-28-2021 15:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry
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**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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-25-2021 17:33:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Feb/25/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or systemi</b> N <b>c symptoms present o</b> O <b>n the last day the Subj</b> <b>ect Diary was complet</b> <b>ed?:</b>	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G  <b>Were fever or system ic symptoms present on the last day the S ubject Diary was co mpleted?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERD MUSCLE PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NEW OR WORSENER M USCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENER JOINT PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

**2.h Symptom:**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD JOI NT PAIN	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.a

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RES DN ES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

5.b

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-25-2021 17:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-26-2021 11:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-26-2021 06:08:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

				review and correct as appropriate.
Feb-25-2021 17:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 17:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 11:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID: BRLYBC</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 11:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BRLYBC	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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: 11561357 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.b

Date	Location	User	Value	Reason
Feb-26-2021 11:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID: BS2F7Y</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 11:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BS2F7Y	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-26-2021 11:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID: BS2F7X</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 11:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BS2F7X	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-28-2021 15:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Consent Was:**

Date	Location	User	Value	Reason
Jan-28-2021 15:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obta ined  Jan/28/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 11:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-29-2021 11:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 11:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 11:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
Unscheduled

**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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jan-29-2021 11:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 11:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BR38W5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 11:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BR38W5	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-29-2021 11:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BS60H8	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
Unscheduled

**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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 11:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BS60H8	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-29-2021 11:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BS60H7	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 11:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BS60H7	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
Unscheduled 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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 11:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-29-2021 11:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 11:38:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 11:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
Unscheduled 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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jan-29-2021 11:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 11:38:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID: BR38WF</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 11:38:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BR38WF	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/09/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-26-2021 12:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Feb/9/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Feb-26-2021 12:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SSWAB_WEEK2	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/09/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-26-2021 12:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-26-2021 12:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-26-2021 12:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 12:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/09/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Feb-26-2021 12:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Feb/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-26-2021 12:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> AA11000	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-26-2021 12:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> AA11000	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/24/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-26-2021 11:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Feb/24/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Feb-26-2021 11:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SSWAB_WEEK4	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/24/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-26-2021 11:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-26-2021 11:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-26-2021 11:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 11:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/24/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Feb-26-2021 11:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Feb/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-26-2021 11:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> AA10955	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-26-2021 11:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> AA10955	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/10/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-12-2021 10:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Mar/10/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Mar-12-2021 10:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SSWAB_WEEK6	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/10/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-12-2021 10:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-12-2021 10:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-12-2021 10:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 10:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/10/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Mar-12-2021 10:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Mar/10/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-12-2021 10:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> AA10965	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-12-2021 10:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> AA10965	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-30-2021 15:27:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Mar/24/2021	Initial Entry

*3. COVID-19 Surveillance Visit:*

Date	Location	User	Value	Reason
May-21-2021 02:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation
May-20-2021 13:54:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	Query 1: Answered	PD HAS BEEN COMPLETED.
May-19-2021 06:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	PDQ: WEEK8 surveillance swab was performed on 24MAR2021 and repeat swab is expected to perform every 10

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				to 18 Days after each surveillance swab Collection. However, repeat swab week 10 is missing. Please clarify the reason for missing swab and confirm PD.
Mar-30-2021 15:27:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SSWAB_WEEK8	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-30-2021 15:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-30-2021 15:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-30-2021 15:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-30-2021 15:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 4 -  
Unscheduled Visit on Mar/24/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Mar-30-2021 15:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Mar/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-30-2021 15:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> AA10954	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-30-2021 15:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> AA10954	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/19/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jun-11-2021 02:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Jun-10-2021 09:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	Query 1: Answered	SUBJECT IS NOT OUT OF WINDOW.SUBJECT SKIPPED PREVIOUS SWAB (WK10)
Jun-09-2021 05:06:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (8 days) from DOV (24/Mar/2021) at SSWAB_WEEK8. Please reconcile and update accordingly, else confirm date is correct as is.
Apr-20-2021 16:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Apr/19/2021	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/19/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-20-2021 16:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SSWAB_WEEK12	Initial Entry



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/19/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-20-2021 16:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-20-2021 16:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-20-2021 16:17:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-20-2021 16:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 5 -  
Unscheduled Visit on Apr/19/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				review and correct as appropriate.
Apr-20-2021 16:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Apr/19/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-20-2021 16:17:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> AA40645	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-20-2021 16:17:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> AA40645	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on May/03/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
May-07-2021 13:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> May/3/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
May-07-2021 13:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SSWAB_WEEK14	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on May/03/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-07-2021 13:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-07-2021 13:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-07-2021 13:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-07-2021 13:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 6 -  
Unscheduled Visit on May/03/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
May-07-2021 13:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  May/3/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-07-2021 13:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> AA40190	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-07-2021 13:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> AA40190	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/13/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
May-14-2021 14:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> May/13/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
May-14-2021 14:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> SSWAB_WEEK16	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/13/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-14-2021 14:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-14-2021 14:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-14-2021 14:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
May-14-2021 14:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Closed	Close Auto Query

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/13/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

May-14-2021 14:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
May-14-2021 14:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  May/13/2021	Transcription Error
May-14-2021 14:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 3: Opened	Date of Collection is different from Date of Visit. Please review and update as appropriate, else clarify.
May-14-2021 14:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
May-14-2021 14:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Date of Assessment is a future date relative to when it was entered.

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 7 -  
Unscheduled Visit on May/13/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				Please correct.
May-14-2021 14:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  May/16/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-14-2021 14:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID: AA40644</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-14-2021 14:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> AA40644	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

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

**Form Version:** 20-Feb-2021 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject No:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-25-2021 17:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Feb/25/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-25-2021 17:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-25-2021 17:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
May-13-2021 15:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> May/13/2021	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
May-13-2021 15:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-13-2021 15:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	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.
May-13-2021 15:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> 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	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

**Subject No:** 11561357

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Form Created	

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Category:**

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Aug-11-2021 06:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 1: Closed	Being tracked separately now
Aug-04-2021 12:17:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 1: Reissued:Candida te	Await SAE FUP
Aug-04-2021 09:57:15	ACV0PF EINFP60	Hector Aguilar	Query 1: Answered	SAE FOLLOW-UP

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		WAS SUBMITTED YESTERDAY. PLEASE CHECK.
Aug-04-2021 03:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 1: Reissued:Opened	MM: The details have not been sent on an SAE FUP form and so are not included on the safety database. Could I kindly ask that the details are provided on an SAE FUP form?
Aug-02-2021 10:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	Query 1: Answered	DETAILS HAVE BEEN PROVIDED.
Jul-28-2021 12:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Donald Scott McVinnie (b) (4)	Query 1: Opened	MM: Please provide details of histopathology on SAE FUP form.
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US &	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> APPENDICITIS	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Canada)

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jun/10/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date Time:  Jun/10/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;**

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

*Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Jun-30-2021 23:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Jun-25-2021 11:41:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Transcription Error
Jun-25-2021 11:41:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?	Transcription Error

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

			<p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
<p>Jun-24-2021 23:43:38 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>Quan Jason Gong (b) (4)</p>	<p>Query 2: Opened</p>	<p>GPDClin: Please clarify which SAE criteria was met for this SAE. The current selection of "life threatening" conflicts with severity Grade 2 as well as what in SAE report as "medically important" event.</p>
<p>Jun-23-2021 05:29:12 (UTC-05:00)</p>	<p>ACV0PF EINFP60 00</p>	<p>auto query (autoquery)</p>	<p>Query 1: Deleted</p>	<p>Close Auto Query</p>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Eastern Time (US & Canada)				
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	For AE APPENDICITIS: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

			NO	
			Is this serious event life threatening?	
			YES	
			Other medically important serious event	
			NO	

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

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jun-30-2021 15:19:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-29-2021 16:51:49	ACV0PF EINFP60	Hector Aguilar	Query 1: Answered	PI STATES THAT IS IS

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		RELATED. THANKS.
Jun-29-2021 16:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Causality is noted as Related to Study Treatment. However Appendicitis is not typically expected to be related. Please confirm if this AE is truly related to study treatment, then update the CRF accordingly.
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jun-22-2021 10:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jun-23-2021 05:29:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 2021749538	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
May-13-2021 15:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> May/13/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
May-13-2021 15:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
May-18-2021 10:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> May/17/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - 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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Consent Was:**

Date	Location	User	Value	Reason
May-18-2021 10:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  May/17/2021	Initial Entry

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
May-18-2021 10:56:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> May/17/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
May-18-2021 10:56:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
May-18-2021 10:56:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
May-18-2021 10:57:52	ACV0PF EINFP60	Hector Aguilar	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
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5. Specimen Type:

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**6.a Test:**

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
May-18-2021 10:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-18-2021 10:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-18-2021 10:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-18-2021 11:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-18-2021 10:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
May-18-2021 10:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  May/17/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-18-2021 11:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BT9SJ7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-18-2021 11:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BT9SJ7	Initial Entry

**5.b**

Date	Location	User	Value	Reason
May-18-2021 11:08:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BKH913	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
May-18-2021 11:08:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BKH913	Initial Entry

**5.c**

Date	Location	User	Value	Reason
May-18-2021 11:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BKH912	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
May-18-2021 11:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BKH912	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-18-2021 10:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-18-2021 10:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-18-2021 11:12:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-18-2021 10:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				correct as appropriate.
May-18-2021 10:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  May/17/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-18-2021 11:12:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BT9SJ1	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-18-2021 11:12:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BT9SJ1	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> May/17/2021 17:20	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**9. Unit:**

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 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
May-18-2021 10:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jun-07-2021 14:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jun/7/2021	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17	ACV0PF EINFP60	Hector Aguilar	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)



Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561357

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00	(b) (4)		
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5. Specimen Type:

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**6.a Test:**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jun-07-2021 14:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jun-08-2021 10:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-07-2021 14:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				appropriate.
Jun-07-2021 14:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jun/7/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jun-08-2021 10:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BT9SMV	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jun-08-2021 10:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> BT9SMV	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jun/7/2021 10:59	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
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090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 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
Jun-07-2021 14:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jul-07-2021 16:23:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jul/6/2021	Initial Entry



**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

**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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Contact Type:**

Date	Location	User	Value	Reason
Jul-07-2021 16:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Jul-07-2021 16:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Contact:  Jul/6/2021	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit  
Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jul-07-2021 16:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jul/6/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jul-07-2021 16:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jul-07-2021 16:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1156

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

**Subject No:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Subject Status**

Date	Location	User	Value	Reason
Feb-25-2021 17:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Jan-08-2021 13:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Jan-08-2021 13:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Jul-07-2021 03:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Erroneous Entry
Jul-06-2021 10:01:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	Query 1: Answered	CONFIRMED ERRONEAOUSLY
Jul-06-2021	ACV0PF	(b) (4), (b) (6)	Query 1: Reissued:Ope	Illness eDiary RQ2:

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

01:45:08 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	ned	Response states 'SUBJECT UNDERWENT AN APPENDECTOMY.' Please confirm if Illness edairy entry on 14Jun21 was deemed erroneous and that subject had no Covid Illness symptoms.
Jul-02-2021 13:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	Query 1: Answered	SUBJECT UNDERWENT AN APPENDECTOMY. THIS IS WHY THE SUBJECTS MOTHER REPORTED SYMPTOMS. THIS INFORMATION HAS BEEN DOCUMENTED ON THE SUBJECT CONTACT LOG AND AE LOG.
Jun-30-2021 12:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Ope ned	Illness eDiary Q1: Thank you for response, please confirm if patient could followed up and confirm if patient has entered eDiary correctly 14Jun2021 and if

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				COVID Illness visit is scheduled else confirm if patient has entered it erroneously. Thank you.
Jun-22-2021 09:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Can didate	DM: Based on site's response, should give enough time to site to follow up with patient, hence should check the data after 1 week.
Jun-21-2021 11:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Hector Aguilar (b) (4)	Query 1: Answered	SUBJECT CALLED ON 15JUN2021. NO ANSWER. MESSAGE LEFT.
Jun-20-2021 12:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 14Jun2021. But there is no COVID Illness visit reported in the database. Please clarify.

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (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:** 11561357

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Feb-25-2021 17:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Feb/25/2021	Initial Entry
Jan-08-2021 13:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Jan/7/2021	Initial Entry
Jan-08-2021 13:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1156

**Subject No:** 11561357

**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):** 10-Nov-2021 20:44

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Mar-23-2021 22:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e19891a045\Final\Final On: 11-Nov-2021 01:21 (GMT)