

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** COHORT SELECTION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**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	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/21/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DEMOGRAPHY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11561160]
2.	Birth Date:	(b) (6)/1958
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DISPOSITION - SCREENING

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[human immunodeficiency virus disease]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cesarean section]
	Start Date:	Nov/11/1974
	Ongoing:	NO End Date: Nov/11/1974
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[newborn delivery]
	Start Date:	Nov/11/1974
	Ongoing:	NO End Date: Nov/11/1974
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cesarean section]
	Start Date:	Dec/20/1983
	Ongoing:	NO End Date: Dec/20/1983

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[newborn delivery]
	Start Date:	Dec/20/1983
	Ongoing:	NO End Date: Dec/20/1983
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cesarean section]
	Start Date:	Dec/31/1987
	Ongoing:	NO End Date: Dec/31/1987
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[newborn delivery]
	Start Date:	Dec/31/1987
	Ongoing:	NO End Date: Dec/31/1987
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cesarean section]
	Start Date:	Oct/8/1991
	Ongoing:	NO End Date: Oct/8/1991

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[newborn delivery]
	Start Date:	Oct/8/1991
	Ongoing:	NO End Date: Oct/8/1991
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anemia]
	Start Date:	Dec/5/2015
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyperlipidemia]
	Start Date:	Dec/5/2015
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[asthma]
	Start Date:	Jan/31/2018
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic low back pain]
	Start Date:	Oct/8/2019
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

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

1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	May/10/2017
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RHINITIS]
	Start Date:	UNK/UNK/2018
	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:** 11561160

**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):** 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is known to be HIV POSITIVE
----	---	---

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LAB CHEMISTRY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[QUEST DIAGNOSTICS-MIAMI, 10200 COMMERCE PARKWAY, MIRAMAR, FL 33025-3938 Laboratory Director: JULIE L FRIEDMAN,MD, CLIA: 10D0277334]
3.	Collection Date:	Aug/4/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[2124]
	Test:	HIV RNA (Ultrasensitive)
	Result:	[NOT DETECTED]
	LNMT	Low [ ] High [<20] Unit /mL

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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[QUEST DIAGNOSTICS-MIAMI, 10200 COMMERCE PARKWAY, MIRAMAR, FL 33025-3938 Laboratory Director: JULIE L FRIEDMAN,MD, CLIA: 10D0277334]
3.	Collection Date:	Aug/4/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[4722]
	Test:	CD4_PX4722
	Result:	[1.102]
	LNMT	Low [0.49] High [1.74] Unit 10^3/mm3

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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/21/2020
2.	Weight:	[73.0]
3.	Unit:	kg
4.	Height:	[143.7]
5.	Unit:	cm
6.	Body Mass Index:	[35.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:51

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[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>

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**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/21/2020
2.	Randomization Number:	[261932]
3.	Randomization Group:	[ ]



**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPHS77]
5.b	Sample ID	[BPHS78]
5.c	Sample ID	[BP18NG]

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**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP18NL]
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/21/2020 14:06
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:** 11561160

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

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

[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
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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/12/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[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>

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2Z1S]
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/12/2020 15:38
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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[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?	Not Done _____	<a href="#">Comments</a>
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
3.	Injection Site Location:	Not Done	<a href="#">Comments</a>
4.	Injection Site Body Side:	Not Done	<a href="#">Comments</a>
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done	<a href="#">Comments</a>

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: LAB CHEMISTRY

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Chemistry Details**

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

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ HIV RNA (Ultrasensitive)	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 15-Sep-2020 21:53

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Laboratory Data Hematology**

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

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ CD4_PX4722	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR69W7]
5.b	Sample ID	[BRZPYP]
5.c	Sample ID	[BRZPYR]

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LAB CHEMISTRY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Lab Chemistry Details**

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

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	LNMT	Low [ ] High [ ] Unit

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Laboratory Data Hematology**

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

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	LNMT	Low [ ] High [ ] Unit

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LAB CHEMISTRY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Lab Chemistry Details**

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

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	LNMT	Low [ ] High [ ] Unit

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Laboratory Data Hematology**

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

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	LNMT	Low [ ] High [ ] Unit

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LAB CHEMISTRY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Lab Chemistry Details**

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

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	LNMT	Low [ ] High [ ] Unit

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Laboratory Data Hematology**

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

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	LNMT	Low [ ] High [ ] Unit

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
----	------------------------	-----

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**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:** 11561160

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

**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:** 11561160

**Subject Initials:** ---

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

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

**Illness Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT Visit

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - 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:** 11561160

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Unplanned Assessments**

1.	Assessments	
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	MOTOR VEHICLE ACCIDENT	Dec/24/2020 UNK:UNK	NO End Date Time:  Dec/24/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[MOTOR VEHICLE ACCIDENT]
4.	Start Date Time:	Dec/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? YES  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? 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.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021018896]

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Medication Error**

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DISPOSITION - TREATMENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Nov/10/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**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:** 11561160

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DISPOSITION - FOLLOW-UP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Dec/24/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
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:** 11561160

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Not Started

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Treatment Unblinded**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DEATH DETAILS CODED

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Dec/24/2020
----	---	-------------

**Cause of Death**

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[MOTOR VEHICLE ACCIDENT]

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/24/2020



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Hector Rodriguez	Approved	Mar-04-2021 12:47:18 (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 Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-21-2020 16:57:32 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1156

**Subject No:** 11561160

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

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

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1156

**Subject No:** 11561160

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

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

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1156

**Subject No:** 11561160

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

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

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**Subject No:** 11561160

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Form	Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LAB CHEMISTRY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LAB CHEMISTRY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LAB CHEMISTRY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LAB CHEMISTRY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	Hector Aguilar (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Nov-10-2020 17:25:25 (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: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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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	Mar-04-2021 12:47:18 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

Hector Aguilar	N/A	Jan-28-2021 12:50:53 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Jan-23-2021 16:42:43 (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	Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Nov-16-2020 15:44:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-13-2020 16:23:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Nov-12-2020 13:05:08 (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.

(b) (6)	N/A	Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Nov-11-2020 14:11:41 (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.

**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:** 11561160

**Subject Initials:** ---

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

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

Hector Aguilar	N/A	Nov-10-2020 15:59:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hector Rodriguez	Approved	Nov-10-2020 12:15:27 (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.

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-21-2020 16:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Consent Was:*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-21-2020 16:56:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/21/2020	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-21-2020 16:56:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11561160	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-21-2020 16:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1958	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-21-2020 16:57:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-21-2020 16:57:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:57:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> BLACK OR AFRICAN AMERIC AN	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

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

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-21-2020 16:57:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-21-2020 16:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-21-2020 16:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-21-2020 16:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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*I.a*

Date	Location	User	Value	Reason
Sep-21-2020 17:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> human immunodeficiency virus disease <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-21-2020 17:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 10:00:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Oct-26-2020 19:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	STABLE ANTIRETROVIRAL THERAPY FOR OVER THREE YEARS.
Oct-26-2020 18:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: In addition to viral load <50 copies/mL and CD4 count >200 cells/mm3 within the past 6 months, Please confirm the subject has been on stable antiretroviral therapy for at least 6 months (Protocol 10.8).

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Sep-21-2020 17:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> human immunodeficiency virus disease	Initial Entry
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**1.a Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Sep-21-2020 17:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> cesarean section <b>Start Date:</b> Nov/11/1974 <b>Ongoing:</b> NO End Date: Nov/11/1974	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> cesarean section	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Nov/11/1974	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date:  Nov/11/1974	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Sep-21-2020 17:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> newborn delivery <b>Start Date:</b> Nov/11/1974 <b>Ongoing:</b> NO End Date:  Nov/11/1974 4	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> newborn delivery	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Nov/11/1974	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date:  Nov/11/1974	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> cesarean section <b>Start Date:</b> Dec/20/1983 <b>Ongoing:</b> NO End Date:  Dec/20/1983	Initial Entry

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Header Text: c4591001

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Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

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

**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> cesarean section	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/20/1983	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date:  Dec/20/1983	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> newborn delivery <b>Start Date:</b> Dec/20/1983 <b>Ongoing:</b> NO End Date:  Dec/20/1983	Initial Entry

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Header Text: c4591001

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Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

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Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

**I.e Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> newborn delivery	Initial Entry

**I.e Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/20/1983	Initial Entry

**I.e Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:12:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date:  Dec/20/1983	Initial Entry

**I.f**

Date	Location	User	Value	Reason
Sep-21-2020 17:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> cesarean section <b>Start Date:</b> Dec/31/1987 <b>Ongoing:</b> NO End Date:  Dec/31/1987	Initial Entry

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Header Text: c4591001

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Subject No: 11561160

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Subject Initials: ---

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

***I.f Line/MH Number:***

Date	Location	User	Value	Reason
Sep-21-2020 17:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

***I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-21-2020 17:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> cesarean section	Initial Entry

***I.f Start Date:***

Date	Location	User	Value	Reason
Sep-21-2020 17:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/31/1987	Initial Entry

***I.f Ongoing:***

Date	Location	User	Value	Reason
Sep-21-2020 17:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date:  Dec/31/1987	Initial Entry

***I.g***

Date	Location	User	Value	Reason
Sep-21-2020 17:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> newborn delivery <b>Start Date:</b> Dec/31/1987 <b>Ongoing:</b> NO End Date:  Dec/31/1987 7	Initial Entry

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Header Text: c4591001

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Subject No: 11561160

Generated By: (b) (4)

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

**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> newborn delivery	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/31/1987	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:14:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date: Dec/31/1987	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Sep-21-2020 17:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> cesarean section <b>Start Date:</b> Oct/8/1991 <b>Ongoing:</b> NO End Date: Oct/8/1991	Initial Entry

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Header Text: c4591001

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Subject No: 11561160

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Subject Initials: ---

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

**I.h Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> cesarean section	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Oct/8/1991	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date: Oct/8/1991	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Sep-21-2020 17:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> newborn delivery <b>Start Date:</b> Oct/8/1991 <b>Ongoing:</b> NO End Date: Oct/8/1991	Initial Entry

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Header Text: c4591001

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Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

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Subject Initials: ---

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***I.i Line/MH Number:***

Date	Location	User	Value	Reason
Sep-21-2020 17:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

***I.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-21-2020 17:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> newborn delivery	Initial Entry

***I.i Start Date:***

Date	Location	User	Value	Reason
Sep-21-2020 17:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Oct/8/1991	Initial Entry

***I.i Ongoing:***

Date	Location	User	Value	Reason
Sep-21-2020 17:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date: Oct/8/1991	Initial Entry

***I.j***

Date	Location	User	Value	Reason
Sep-21-2020 17:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>Medical History Term</b> anemia : <b>Start Date:</b> Dec/5/2015 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Site No: 1156

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Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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*I.j Line/MH Number:*

Date	Location	User	Value	Reason
Sep-21-2020 17:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

*I.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Sep-23-2020 15:14:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 10:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	No blood products received.
Sep-22-2020 20:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Anemia reported: Please confirm if subject has received any blood products in the past 60 days for this medhx.
Sep-21-2020 17:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> anemia	Initial Entry

*I.j Start Date:*

Date	Location	User	Value	Reason
Sep-21-2020 17:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/5/2015	Initial Entry

*I.j Ongoing:*

Date	Location	User	Value	Reason
Sep-21-2020 17:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

*I.k*

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Date	Location	User	Value	Reason
Sep-21-2020 17:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>Medical History Term:</b> hyperlipidem ia <b>Start Date:</b> Dec/5/2015 <b>Ongoing:</b> YES	Initial Entry

*I.k Line/MH Number:*

Date	Location	User	Value	Reason
Sep-21-2020 17:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

*I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Sep-21-2020 17:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> hyperlipidemia	Initial Entry

*I.k Start Date:*

Date	Location	User	Value	Reason
Sep-21-2020 17:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/5/2015	Initial Entry

*I.k Ongoing:*

Date	Location	User	Value	Reason
Sep-21-2020 17:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

*I.l*

Date	Location	User	Value	Reason
Sep-21-2020 17:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 12 <b>Medical History Term</b> asthma :	Initial Entry

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Subject No: 11561160

Generated By: (b) (4)

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			<b>Start Date:</b>	Jan/31/2018	
			<b>Ongoing:</b>	YES	

**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

**1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> asthma	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Jan/31/2018	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Sep-21-2020 17:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History:</b> chronic low back pain <b>Term:</b> <b>Start Date:</b> Oct/8/2019 <b>Ongoing:</b> YES	Initial Entry

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**I.m Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

**I.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> chronic low back pain	Initial Entry

**I.m Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Oct/8/2019	Initial Entry

**I.m Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**I.n**

Date	Location	User	Value	Reason
Sep-21-2020 17:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 14 <b>Medical History Term:</b> Gastroesophageal reflux disease <b>Start Date:</b> May/10/2017 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Subject No: 11561160

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**I.n Line/MH Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

**I.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-21-2020 17:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Gastroesophageal reflux disease	Initial Entry

**I.n Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> May/10/2017	Initial Entry

**I.n Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**I.o**

Date	Location	User	Value	Reason
Nov-11-2020 13:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 15 <b>Medical History Te</b> RHINITIS <b>rm:</b> <b>Start Date:</b> UNK/UNK/20 18 <b>Ongoing:</b> YES	Initial Entry

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Subject Initials: ---

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**I.o Line/MH Number:**

Date	Location	User	Value	Reason
Nov-11-2020 13:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

**I.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Nov-11-2020 13:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> RHINITIS	Initial Entry

**I.o Start Date:**

Date	Location	User	Value	Reason
Nov-11-2020 13:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**I.o Ongoing:**

Date	Location	User	Value	Reason
Nov-11-2020 13:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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: 15-Sep-2020 21:57

Site No: 1156

Subject No: 11561160

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): 29-Mar-2021 12:23

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*1. Select appropriate response - What is the subject HIV status?*

Date	Location	User	Value	Reason
Nov-10-2020 02:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per site confirmation - updated PD tracker
Nov-09-2020 15:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	YES, YOU ARE CORRECT. DOSE 2 VACCINE REACTOGENICITY WAS NOT ACTIVATED AT VISIT 2. STAFF MEMBER IS AWARE AND HAS BEEN RETRAINED ON THIS PD.
Nov-09-2020 05:16:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ : Response to What is the subject HIV status? is "The subject is known to be HIV POSITIVE", however eDairy data is missing for this subject for Vaccination 2. Please review and update if the diary data is available else provide a clarification.
Sep-24-2020 18:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 16:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPDATED
Sep-22-2020 20:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Since subject is known to be HIV Positive, please complete the HIV RNA and CD4 CRFs as per Protocol Sec 10.8

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

**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):** 29-Mar-2021 12:23

Sep-21-2020 17:03:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> The subject is known to be HIV POSITIVE	Initial Entry
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:55

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> QUEST DIAGNOSTICS-MIAMI , 10200 COMMERCE PARKWA Y, MIRAMAR, FL 33025-3938 L aboratory Director: JULIE L FRI EDMAN,MD, CLIA: 10D027733 4	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/4/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 2124 <b>Identifier:</b> <b>Test::</b> HIV RNA (Ultra sensitive) <b>Result::</b> NOT DETECTE D	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:55

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

			Lab Normal Range: <i>High</i> <20  Unit /mL	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2124	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HIV RNA (Ultrasensitive)	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-17-2020 07:33:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per site response
Oct-16-2020 14:59:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 2: Answered	VALUE READS "NOT DETECTED" PLEASE CHECK WITH SOURCE IN FLORENCE. THANK YOU.
Oct-14-2020 06:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Opened	Lab Result is not valid and should be a numeric value. Please review and update as necessary based on the Reference

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:55

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

				Range provided in the Lab Records (please ensure no commas or ranges). (b) (4)
Sep-24-2020 01:58:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 16:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DETECTED	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-26-2020 04:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site response
Sep-25-2020 14:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	based on the medical records, subjects HIV 1 RNA, QN PCR results are <20 NOT DETECTED. Thus, <20 would be

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:55

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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				the low normal range. Is this what you require?
Sep-25-2020 01:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Kindly review and update 'Low normal range' as per completion requirement section 8.22.5. Else please clarify.
Sep-24-2020 14:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	Original value is correct
Sep-24-2020 01:58:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Result is present, but lab normal range (Low) is missing. Please correct or confirm.
Sep-23-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> High <20  Unit /mL	Initial Entry

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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> QUEST DIAGNOSTICS-MIAMI , 10200 COMMERCE PARKWA Y, MIRAMAR, FL 33025-3938 L aboratory Director: JULIE L FRI EDMAN,MD, CLIA: 10D027733 4	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/4/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-13-2020 16:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 4722 <b>entifier:</b> <b>Test::</b> CD4_PX4 722 <b>Result::</b> 1.102	Changed Information

**Header Text:** c4591001

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

**Form:** LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:53

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

			<b>Lab Normal Range:</b> <i>Low</i> 0.49  <i>High</i> 1.74  Unit 10 <sup>3</sup> /m m3	
Nov-13-2020 16:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 4722 <b>Test::</b> CD4_PX4 722 <b>Result::</b> 1.102 <b>Lab Normal Range:</b> <i>Low</i> 490  <i>High</i> 1740  Unit 10 <sup>3</sup> /m m3	Changed Information
Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 4722 <b>Test::</b> CD4_PX4 722 <b>Result::</b> 1102 <b>Lab Normal Range:</b> <i>Low</i> 490  <i>High</i> 1740  Unit 10 <sup>3</sup> /m m3	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1156**Site Name:** (1156) Acevedo Clinical Research Associates**Subject No:** 11561160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4722	Initial Entry
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**5.a Test:**

Date	Location	User	Value	Reason
Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CD4_PX4722	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Nov-16-2020 02:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Nov-13-2020 16:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-13-2020 16:23:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.102	Changed Information
Nov-12-2020 21:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please enter the CD4 absolute values only, LNMT Low and LNMT High, after dividing the number by 1000 to allow using the Unit provided "10 <sup>3</sup> /mm <sup>3</sup> " equivalent to "1000/mm <sup>3</sup> "
Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1102	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Nov-13-2020 16:24:22 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low	Changed Information

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Time (US & Canada)		(b) (4), (b) (6)	0.49 <i>High</i> 1.74  Unit 10 <sup>3</sup> /mm <sup>3</sup>	
Sep-23-2020 16:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 490  <i>High</i> 1740  Unit 10 <sup>3</sup> /mm <sup>3</sup>	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> 73.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> 143.7	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35.4	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.6 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> 97.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 17:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Test::</b>	Not Applicable
			<b>Result::</b>	Not Applicable
			<b>Not Done::</b>	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-21-2020 17:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

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

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

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

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-21-2020 17:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> 261932	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-21-2020 17:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-21-2020 17:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-21-2020 17:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 17:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 17:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Sep/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-21-2020 17:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID: BPHS77</b>	Initial Entry

**5.a Sample ID**

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-21-2020 17:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> BPHS77	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 17:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPHS78	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> BPHS78	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 17:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BP18NG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> BP18NG	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-21-2020 17:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-21-2020 17:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-21-2020 17:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 17:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 17:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Sep/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-21-2020 17:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Sample ID: BP18NL	Initial Entry

**5.a Sample ID**

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-21-2020 17:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> BP18NL	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-21-2020 17:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-21-2020 17:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-21-2020 17:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-19-2020 05:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation
Oct-16-2020 09:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EDIARY WAS NOT ABLE TO BE ACTIVATED UNTIL 9/25. VACCINE WAS GIVEN 9/21
Oct-14-2020 04:38:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per eDiary records, vaccination date is 25-Sep-2020. Please reconcile or confirm in the query response as appropriate.
Sep-21-2020 17:25:20	ACV0PFEINFP6000	Hector Aguilar	<b>Data Entry:</b>	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)	(b) (4)	Sep/21/2020 14:06
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 17:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 17:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 17:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-21-2020 17:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED 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
Sep-21-2020 17:25:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-23-2020 16:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	New Information
Sep-21-2020 17:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

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

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-13-2020 11:51:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Oct/12/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?:</b> NO	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

*2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?*

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FAT IG UE	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: 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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Data Entry: Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> 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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?:</b> NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> 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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:</b>	Initial Entry  VO MIT ING  NO
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**2.e Symptom:**

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:</b>	Initial Entry  DIA RR HE A  NO

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUS CLE PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD MUSCLE 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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.h

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?:</b> NO	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PA IN	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reaction s present on the last day the Subject Diary was complete d?:</b> NO	Initial Entry
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**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactio ns present on the last day t he Subject Diary was comp leted?:</b> NO	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Oct-13-2020 12:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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*1. Date:*

Date	Location	User	Value	Reason
Oct-13-2020 11:56:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> Oct/12/2020	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Oct-13-2020 11:56:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Locat ion:: ORAL CAVI TY	Initial Entry

*2.a Record Identifier:*

Date	Location	User	Value	Reason
Oct-13-2020 11:56:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> 1	Initial Entry

*2.a Temperature:*

Date	Location	User	Value	Reason
Oct-13-2020 11:56:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> 97.8	Initial Entry

*2.a Unit:*

Date	Location	User	Value	Reason
Oct-13-2020 11:56:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<u>Data Entry:</u> F	Initial Entry

*2.a Temperature Location:*

Date	Location	User	Value	Reason
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Oct-13-2020 11:56:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Test::</b>	Not Applicable
			<b>Result::</b>	Not Applicable
			<b>Not Done::</b>	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-13-2020 11:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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*1. Data Origin*

Date	Location	User	Value	Reason
Oct-13-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

*2. Sample Type*

Date	Location	User	Value	Reason
Oct-13-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

*3. Sample Collected?*

Date	Location	User	Value	Reason
Oct-13-2020 12:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Oct/12/2020	Initial Entry

*5.a*

Date	Location	User	Value	Reason
Oct-13-2020 12:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Sample ID: BR2Z1S	Initial Entry

*5.a Sample ID*

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Oct-13-2020 12:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> BR2Z1S	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Oct/12/2020 15:38	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

**7. Route:**

Date	Location	User	Value	Reason
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBS ERVATION 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
Oct-13-2020 11:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1156

**Subject No:** 11561160

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

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

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-10-2020 16:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Nov/10/2020	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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*I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?*

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_01
Nov-11-2020 14:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-11-2020 03:32:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346236;Were medications to treat fever/pain given on the last day the Subject Diary was completed? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

2.a

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Appl icabl e  <b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Don e	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> Not Appl icabl e  <b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Appl icabl e	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query I: Clo sed	Auto closed by Validation Check: VC_FAVSD011_02
Nov-11-2020 14:40:59 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Query I: Ans wered	Changed data per query

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Nov-11-2020 03:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346160;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry</b> : Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  Not Applicable  Not Done
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  Not Applicable  Not Applicable

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_02
Nov-11-2020 14:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Nov-11-2020 03:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346161;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry</b> : Not Applicable	Initial Entry

2.c

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Don e</p>	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Appl icabl e</p>	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_02
Nov-11-2020 14:41:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Nov-11-2020 03:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346162;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry</b> : Not Applicable	Initial Entry

2.d

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Don e</p>	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Appl icabl e</p>	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

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Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_02
Nov-11-2020 14:47:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Nov-11-2020 03:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346163;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry</b> : Not Applicable	Initial Entry

2.e

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1156

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

**Subject No:** 11561160

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Don e</p>	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Appl icabl e</p>	Initial Entry

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Header Text: c4591001

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Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_02
Nov-11-2020 14:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Nov-11-2020 03:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346164;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry</b> : Not Applicable	Initial Entry

2.f

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Header Text: c4591001

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Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Don e</p>	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Appl icabl e</p>	Initial Entry

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Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_02
Nov-11-2020 14:47:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Nov-11-2020 03:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346165;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry</b> : Not Applicable	Initial Entry

2.g

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Header Text: c4591001

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Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Don e</p>	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Appl icabl e</p>	Initial Entry

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Site No: 1156

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Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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**2.g Symptom:**

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_02
Nov-11-2020 14:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Nov-11-2020 03:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346166;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry</b> : Not Applicable	Initial Entry

**2.h**

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

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Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Don e</p>	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Appl icabl e</p> <p><b>Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:</b> Not Appl icabl e</p>	Initial Entry

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Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_02
Nov-11-2020 14:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Nov-11-2020 03:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346167;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry</b> : Not Applicable	Initial Entry

3. Injection Site Location:

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Site No: 1156

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Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Appl icabl e <b>Were injection site reacti ons present on the last da y the Subject Diary was c ompleted?:</b> Not Done	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Appl icabl e <b>Were injection site reacti ons present on the last da y the Subject Diary was c ompleted?:</b> Not Appl icabl e	Initial Entry

**5.a Injection Site Reaction:**

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Visit: V3\_MONTH1\_POSTVAX2\_L

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Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_03
Nov-11-2020 14:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-11-2020 03:38:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346139;Reactions Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

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

Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Appl icabl e <b>Were injection site reacti ons present on the last da y the Subject Diary was c ompleted?:</b> Not Done	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Appl icabl e <b>Were injection site reacti ons present on the last da y the Subject Diary was c ompleted?:</b> Not Appl icabl e	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_03
Nov-11-2020 14:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-11-2020 03:38:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346140;Reactions Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Appl icabl e  <b>Were injection site reacti</b> Not <b>ons present on the last da</b> Done <b>y the Subject Diary was c</b> <b>ompleted?:</b>	Initial Entry
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Appl icabl e  <b>Were injection site reacti</b> Not <b>ons present on the last da</b> Appl <b>y the Subject Diary was c</b> icabl <b>ompleted?:</b> e	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-11-2020 18:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_FAVSD011_03
Nov-11-2020 14:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 14:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-11-2020 03:38:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5346141;Reactions Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-10-2020 16:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 15-Sep-2020 21:55

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-10-2020 17:25:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-10-2020 17:21:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-10-2020 17:21:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-10-2020 17:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 17:21:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 17:21:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Nov/10/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-10-2020 17:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Sample ID: BR69W7	Initial Entry

**5.a Sample ID**

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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: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-10-2020 17:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> BR69W7	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-10-2020 17:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BRZPYP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-10-2020 17:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> BRZPYP	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-10-2020 17:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BRZPYR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-10-2020 17:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> BRZPYR	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Jan-25-2021 17:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thank you for the response. This query would be addressed by CRA.
Jan-20-2021 11:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	FUP VISIT HAS BEEN COMPLETED. REGARDING ADDITIONAL INFORMATION, THE EMERGENCY CONTACT WAS CALLED BUT HE/SHE DID NOT WANT TO PROVIDE ANY INFORMATION PAST THE FACT THAT THE SUBJECT HAD BEEN IN A MVA.
Jan-18-2021 09:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_ Per report, the subject has died. However, information on clinical course, workup (including

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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: 11561160

Subject Initials: ---

Generated By: (b) (4)

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				imaging) are not described. Kindly provide additional information in a FU report. Thank you.
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> MOTOR VEHICLE ACCIDENT	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/24/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO End Date Time: Dec/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-14-2021 23:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE MOTOR VEHICLE ACCIDENT : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<p><b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>YES</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry
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**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s ) , this event is due to:  OTHER  If Other, specify:  UNKNOWN	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	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
Jan-14-2021 16:06:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1156

Site Name: (1156) Acevedo Clinical Research Associates

Subject No: 11561160

Subject Initials: ---

Generated By: (b) (4)

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

Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death on the Death Details form is not completed. Please review and update as appropriate.
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> FATAL	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021 16:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-14-2021 23:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021018896	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-10-2020 15:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Nov/10/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-10-2020 15:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-10-2020 15:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1156**Subject No:** 11561160**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-21-2021 05:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 15:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Jan-20-2021 11:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Jan-20-2021 11:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-20-2021 11:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/24/2020	Initial Entry
Jan-19-2021 06:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Fatal MVA reported - please complete FUP tab to report end of study
Jan-18-2021 04:54:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021018896, the date of death was reported as 24Dec2020 in Safety database but missing in AE CRF. Please confirm correct date of death. If safety update is required, please submit a follow-up form.

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-20-2021 11:44:19 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

(US & Canada)				
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**3. Status:**

Date	Location	User	Value	Reason
Jan-20-2021 11:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> DEATH	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1156**Subject No:** 11561160**Generated By:** (b) (4)**Form:** DEATH DETAILS CODED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1156) Acevedo Clinical Research Associates**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Date of Collection / Notification of Death:**

Date	Location	User	Value	Reason
Jan-29-2021 02:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-28-2021 12:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	UPDATED
Jan-26-2021 15:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please enter the cause of death on the form.
Jan-26-2021 11:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	Query 1: Answered	MVA
Jan-23-2021 22:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Please report cause of death.
Jan-14-2021 16:06:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Dec/24/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-28-2021 12:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> <b>Cause of Death Status:</b> PRIMARY CAUS E OF DEATH <b>Cause of Death:</b> MOTOR VEHICL E ACCIDENT	Initial Entry

**2.a Cause of Death Status:**

Date	Location	User	Value	Reason
Jan-28-2021 12:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> PRIMARY CAUSE OF DEATH	Initial Entry

**2.a Cause of Death:**

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Jan-28-2021 12:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> MOTOR VEHICLE ACCIDENT	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1156

Subject No: 11561160

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1156) Acevedo Clinical Research Associates

Subject Initials: ---

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Jan-20-2021 11:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Nov-10-2020 15:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-21-2020 17:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-21-2020 16:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Jan-20-2021 11:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/24/2020	Initial Entry
Jan-14-2021 23:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event entered in ae crf
Jan-13-2021 07:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021018896motor vehicle accident(onset date:24Dec2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-10-2020 15:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/10/2020	Initial Entry
Sep-21-2020 17:24:15 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

Time (US & Canada)				
Sep-21-2020 16:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

090177e196ae30bc\Final\Final On: 01-Apr-2021 04:15 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1156

**Subject No:** 11561160

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-10-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hector Aguilar (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry