

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/8/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11291166]
2.	Birth Date:	(b) (6)/1942
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DATE OF VISIT

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/8/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Sep/8/2020
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: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Surgical tape allergy]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diarrhea]
	Start Date:	Dec/UNK/2019
	Ongoing:	NO End Date: Mar/UNK/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[esophageal stricture]
	Start Date:	Mar/UNK/2020
	Ongoing:	NO End Date: Apr/UNK/2020
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hiatal hernia]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left cataracts]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right cataracts]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[myopia]
	Start Date:	UNK/UNK/1965
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyperopia]
	Start Date:	UNK/UNK/1965
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hearing loss]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

1.j	Line/MH Number:	[10]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral astigmatism]	
	Start Date:	UNK/UNK/1955	
	Ongoing:	YES	
1.k	Line/MH Number:	[11]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteoporosis]	
	Start Date:	UNK/UNK/2018	
	Ongoing:	YES	
1.l	Line/MH Number:	[12]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypercholesterolemia]	
	Start Date:	UNK/UNK/2009	
	Ongoing:	YES	
1.m	Line/MH Number:	[13]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depression]	
	Start Date:	UNK/UNK/1950	
	Ongoing:	YES	
1.n	Line/MH Number:	[14]	<a href="#">Comments</a>
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ <del>history of tobacco use</del> ]	<a href="#">Comments</a>
	Start Date:	<del>Jan/15/2021</del>	<a href="#">Comments</a>
	Ongoing:	<del>YES</del>	<a href="#">Comments</a>

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/8/2020
2.	Weight:	[130.0]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[22.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[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:** 1129

**Subject No:** 11291166

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

**Form:** RANDOMIZATION

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/8/2020
2.	Randomization Number:	[248584]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/8/2020
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	[BP5PMS]
5.b	Sample ID	[BP5PMT]
5.c	Sample ID	[BP5PMV]
5.d	Sample ID	[BLD0VY]
5.e	Sample ID	[BLD0VZ]

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/8/2020
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	[BMB5FV]
-----	-----------	----------

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** VACCINATION

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[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/8/2020 13:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DATE OF VISIT

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Sep/28/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Vital Signs**

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

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPBZYB]
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090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** VACCINATION

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[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/28/2020 12:15
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

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DATE OF VISIT

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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

**Date of Visit**

1.	Date of Visit	Oct/26/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/26/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BL9S4P]
5.b	Sample ID	[BL9S4R]
5.c	Sample ID	[BR6XTM]
5.d	Sample ID	[BR6XTN]
5.e	Sample ID	[BR6XTP]

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**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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090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Subject No:** 11291166

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**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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090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Subject No:** 11291166

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**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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090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**Illness Details**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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 Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/26/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DISPOSITION - FOLLOW-UP

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation/Death :	Feb/3/2021	
2.	Phase of Disposition:	FOLLOW-UP	
3.	Status:	DEATH	<a href="#">Comments</a>
4.	Specify Status:	[ ]	

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	myocardial infarction	Feb/3/2021 UNK: UNK	NO End Date Time: Feb/3/2021 UNK:UNK	<a href="#">Repeating Pages</a>

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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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)	[myocardial infarction]
4.	Start Date Time:	Feb/3/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/3/2021 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

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Not Complete

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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: [hyperlipidemia]
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	[2021124008]

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1. DELETED	MEDICATION ERROR	Potential Administration of Incorrect Dosage	Sep/8/2020	NO End Date:  Sep/8/2020	NO ACTION TAKEN	<a href="#">Repeating Pages</a>

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Data Complete, Deleted, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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

**Medication Error**

1.	Category:	MEDICATION ERROR
2.	Medication Error (Type of Medication Error):	[Potential Administration of Incorrect Dosage]
3.	Start Date:	Sep/8/2020
4.	Is the medication error still ongoing?	NO End Date: Sep/8/2020
5.	Latest Action Taken with Study Treatment:	NO ACTION TAKEN
6.	Was a Concomitant Medication given?	NO
7.	Was a Non-Drug Treatment given?	NO
8.	Did the Medication Error cause the subject to be discontinued from the study?	NO
9.	Was this medication error associated with any adverse events?	NO
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)



**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials**

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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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:	//

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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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?	

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[Back to Form](#)

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:	

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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?	

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**Informed Consent - Asymptomatic Surveillance**

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



**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/30/2020
2.	Erroneous Visit	

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Dec/31/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DEATH DETAILS CODED

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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

**Death Details**

1.	Date of Collection / Notification of Death:	Feb/5/2021	<a href="#">Comments</a>
----	---	------------	--------------------------

**Cause of Death**

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Myocardial Infarction]
<del>2.b</del>	Cause of Death Status:	SECONDARY CAUSE OF DEATH
	Cause of Death:	[Hyperlipidemia]

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Feb/3/2021



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

[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, Verified

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Sep-08-2020 14:18:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
1 n	Mar-05-2021 13:20:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	no official start date. Subject denied all tobacco use during screening. Medical records indicate chronic tobacco use however no start date was provided. Date of visit referencing tobacco use is 15Jan2021

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
1 n	Mar-05-2021 13:20:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	no official start date. Subject denied all tobacco use during screening. Medical records indicate chronic tobacco use however no start date was provided. Date of visit referencing tobacco use is 15Jan2021

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
1 n	Mar-05-2021 13:20:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	no official start date. Subject denied all tobacco use during screening. Medical records indicate chronic tobacco use however no start date was provided. Date of visit referencing tobacco use is 15Jan2021

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
1 n	Mar-05-2021 13:20:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	no official start date. Subject denied all tobacco use during screening. Medical records indicate chronic tobacco use however no start date was provided. Date of visit referencing tobacco use is 15Jan2021

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-09-2021 12:06:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	05Feb2021 date site was updated on subjects death, no confirmed date of death, subject found dead 03Feb2021

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-19-2021 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Feb-18-2021 13:54:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-19-2021 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Feb-18-2021 13:54:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Unknown

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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, Verified

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Michael Koren	Approved	Jan-25-2021 18:21:58 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, MichaelKoren, 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.

Alex Hill	N/A	Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
-----------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Michael Koren	Approved	Nov-02-2020 17:13:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, MichaelKoren, 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.

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-08-2020 14:15:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:15:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-08-2020 14:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained  Sep/8/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-08-2020 14:14:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11291166	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:13:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1942	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-08-2020 14:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-08-2020 14:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-08-2020 14:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Sep-08-2020 14:18:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-08-2020 14:18:42 (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-08-2020 14:18:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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*1.a*

Date	Location	User	Value	Reason
Sep-08-2020 14:22:49 (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> Surgical tape allergy <b>Start Date:</b> UNK/UNK/1980 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-08-2020 14:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Surgical tape allergy	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Sep-08-2020 14:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1980	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Sep-08-2020 14:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

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*I.b*

Date	Location	User	Value	Reason
Sep-08-2020 14:23:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>r:</b> <b>Medical History:</b> diarrhea <b>Term:</b> <b>Start Date:</b> Dec/UNK/2019 <b>Ongoing:</b> NO <b>End Date:</b> Mar/UNK/2020	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

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Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Date	Location	User	Value	Reason
Sep-08-2020 14:23:20 (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-08-2020 14:23:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> diarrhea	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:23:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/UNK/2019	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 14:23:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Mar/UNK/2020	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Sep-08-2020 14:24:33 (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> esophageal stricture <b>Start Date:</b> Mar/UNK/2020	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Generated Time (GMT): 29-Mar-2021 11:25

			Ongoing:	NO End Date:  Apr/UNK/2020
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-08-2020 14:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> esophageal stricture	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Mar/UNK/2020	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 14:24:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  Apr/UNK/2020	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Sep-08-2020 14:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 4 :	Initial Entry

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Header Text: c4591001

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Subject No: 11291166

Generated By: (b) (4)

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			<b>Medical History Term:</b> <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES
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**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Sep-08-2020 14:25:05 (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-08-2020 14:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hiatal hernia	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 14:25:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Sep-08-2020 14:34:10 (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> left cataracts	Initial Entry

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Header Text: c4591001

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Subject No: 11291166

Generated By: (b) (4)

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Generated Time (GMT): 29-Mar-2021 11:25

			<b>Start Date:</b>	UNK/UNK/2017
			<b>Ongoing:</b>	YES

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

Date	Location	User	Value	Reason
Sep-08-2020 14:34:10 (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-08-2020 14:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> left cataracts	Initial Entry

**I.e Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**I.e Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 14:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.f**

Date	Location	User	Value	Reason
Sep-08-2020 14:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> r: <b>Medical History Term:</b> right cataracts <b>Start Date:</b> UNK/UNK/2017	Initial Entry

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Subject No: 11291166

Generated By: (b) (4)

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			Ongoing:	NO End Date:  UNK/UNK/ 2017
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*1.f Line/MH Number:*

Date	Location	User	Value	Reason
Sep-08-2020 14:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> right cataracts	Initial Entry

*1.f Start Date:*

Date	Location	User	Value	Reason
Sep-08-2020 14:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2017	Initial Entry

*1.f Ongoing:*

Date	Location	User	Value	Reason
Sep-08-2020 14:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  UNK/UNK/2017	Initial Entry

*1.g*

Date	Location	User	Value	Reason
Sep-08-2020 14:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Line/MH Numbe r: 7	Transcription Error

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)



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**Subject No:** 11291166

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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			<b>Medical History</b> myopia <b>Term:</b> <b>Start Date:</b> UNK/UNK/ 1965 <b>Ongoing:</b> YES	
Sep-08-2020 14:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History</b> nearsighted <b>Term:</b> <b>Start Date:</b> UNK/UNK/ 1965 <b>Ongoing:</b> YES	Initial Entry

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Subject No: 11291166

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-08-2020 14:35:11 (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-08-2020 14:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> myopia	Transcription Error
Sep-08-2020 14:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nearsighted	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1965	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 14:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Sep-08-2020 14:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 8 : <b>Medical History T</b> hyperopia <b>erm:</b> <b>Start Date:</b> UNK/UNK/1 965 <b>Ongoing:</b> YES	Initial Entry

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Subject No: 11291166

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-08-2020 14:35:47 (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-08-2020 14:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hyperopia	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1965	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 14:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Sep-08-2020 14:36:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 9 : <b>Medical History T</b> hearing loss <b>erm:</b> <b>Start Date:</b> UNK/UNK/2 017 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:36:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:36:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> hearing loss	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Sep-08-2020 14:36:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2017	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Sep-08-2020 14:36:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

***1.j***

Date	Location	User	Value	Reason
Sep-08-2020 14:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 10 Medical History: bilateral astigmatism Term: atism Start Date: UNK/UNK/1955 Ongoing: YES	Initial Entry

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***1.j Line/MH Number:***

Date	Location	User	Value	Reason
Sep-08-2020 14:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> bilateral astigmatism	Initial Entry

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***1.j Start Date:***

Date	Location	User	Value	Reason
Sep-08-2020 14:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1955	Initial Entry

***1.j Ongoing:***

Date	Location	User	Value	Reason
Sep-08-2020 14:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.k***

Date	Location	User	Value	Reason
Sep-08-2020 14:57:52 (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> osteoporosis <b>Start Date:</b> UNK/UNK/2 018 <b>Ongoing:</b> YES	Initial Entry

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Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-08-2020 14:57:52 (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-08-2020 14:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> osteoporosis	Initial Entry

**I.k Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**I.k Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 14:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.l**

Date	Location	User	Value	Reason
Sep-08-2020 14:58:59 (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> hypercholesterolemia <b>Start Date:</b> UNK/UNK/2009 <b>Ongoing:</b> YES	Initial Entry

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**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Sep-08-2020 14:58:59 (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-08-2020 14:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypercholesterolemia	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 14:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2009	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 14:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Sep-08-2020 15:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 13 : Medical History T depression erm: Start Date: UNK/UNK/1 950 Ongoing: YES	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Sep-08-2020 15:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 13	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 09:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-05-2021 13:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-03-2021 08:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per report, "noted that tobacco use probably contributed to death." However, history of tobacco use has not been recorded in this form. Pls revise and update accordingly.
Sep-08-2020 15:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> depression	Initial Entry

**I.m Start Date:**

Date	Location	User	Value	Reason
Sep-08-2020 15:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1950	Initial Entry

**I.m Ongoing:**

Date	Location	User	Value	Reason
Sep-08-2020 15:01:11 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)

(b) (4), (b) (6)

*l.n*

Date	Location	User	Value	Reason
Mar-11-2021 17:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Num</b> 14 <b>ber:</b> <b>Medical Histor</b> history of toba <b>y Term:</b> cco use <b>Start Date:</b> Jan/15/2021 <b>Ongoing:</b> YES	Transcription Error <b>(DELETED)</b>
Mar-05-2021 13:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 14 <b>ber:</b> <b>Medical Histor</b> history of toba <b>y Term:</b> cco use <b>Start Date:</b> Jan/15/2021 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Mar-11-2021 17:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14	Transcription Error <b>(DELETED)</b>
Mar-05-2021 13:15:45 (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
Mar-11-2021 17:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>history of tobacco use</del>	Transcription Error <b>(DELETED)</b>
Mar-05-2021 13:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> history of tobacco use	Initial Entry

***I.n Start Date:***

Date	Location	User	Value	Reason
Mar-12-2021 03:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Closed	Response satisfies query
Mar-12-2021 00:32:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	data deleted
Mar-11-2021 17:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Mar-11-2021 17:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>Jan/15/2021</del>	Transcription Error <b>(DELETED)</b>
Mar-11-2021 17:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Start Date is after or equal to the first vaccination date 08/Sep/2020. Please review and update

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

				as appropriate.
Mar-11-2021 17:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-10-2021 08:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Opened	P21 Review: Start Date 15Jan2021 is after Vaccination date 08Sep2020. If event started after vaccination, kindly remove the event from here and update in AE log. Else clarify.
Mar-09-2021 14:24:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 11:22:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	start year is unknown per previous query response.
Mar-08-2021 08:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Partial dates are allowed at history data. If exact day and month is not know, UNK can be used. Thank you.
Mar-05-2021 13:24:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	start date not provided. Subject denied any tobacco use during screening. Medical records provided indicate chronic tobacco use, however no start date is provided. The visit referencing chronic tobacco use is dated 15Jan2021.

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**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

Mar-05-2021 13:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 08/Sep/2020. Please review and update as appropriate.
Mar-05-2021 13:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021	Initial Entry

***In Ongoing:***

Date	Location	User	Value	Reason
Mar-11-2021 17:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>YES</del>	Transcription Error <b>(DELETED)</b>
Mar-05-2021 13:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Date:**

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/8/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 130.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 64.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 22.3	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.4 <b>Temperature Unit</b> F : <b>Temperature Loca</b> ORAL CAV <b>tion::</b> ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-08-2020 15:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No 11291166

Subject Initials

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test:</b> Not Applicable <b>Result:</b> Not Applicable <b>Not Done:</b> Not Applicable	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-08-2020 15:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-08-2020 15:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-08-2020 15:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 248584	Initial Entry

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: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 10:04:13 (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-09-2020 10:04:13 (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-09-2020 10:04:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 10:04:13 (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-09-2020 10:04:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/8/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-09-2020 10:04:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5PMS	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No 11291166

Subject Initials

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 10:04:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5PMS	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-09-2020 10:04:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP5PMT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 10:04:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5PMT	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-09-2020 10:04:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP5PMV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 10:04:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5PMV	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-09-2020 10:04:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLD0VY	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials**

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**5.d Sample ID**

Date	Location	User	Value	Reason
Sep-09-2020 10:04:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLD0VY	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Sep-09-2020 10:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLD0VZ	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Sep-09-2020 10:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLD0VZ	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 10:05:26 (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-09-2020 10:05:26 (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-09-2020 10:05:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 10:05:26 (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-09-2020 10:05:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/8/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-09-2020 10:05:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BMB5FV	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials**

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-09-2020 10:05:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMB5FV	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-08-2020 15:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-08-2020 15:08:19 (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-08-2020 15:08:19 (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
Sep-08-2020 15:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020 13:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-08-2020 15:08:19 (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-08-2020 15:08:19 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)

(b) (4), (b) (6)

7. Route:

Date	Location	User	Value	Reason
Sep-08-2020 15:08:19 (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-08-2020 15:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION 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-08-2020 15:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-08-2020 15:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

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

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-28-2020 13:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Date:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 97.3 <b>Temperature Unit</b> F : <b>Temperature Location:</b> ORAL CAV <b>ity:</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No 11291166

Subject Initials

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Sep-28-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 12:10:28 (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-30-2020 12:10:28 (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-30-2020 12:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 12:10:28 (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-30-2020 12:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-30-2020 12:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPBZYB	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials**

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-30-2020 12:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPBZYB	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-28-2020 13:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-28-2020 13:14:12 (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-28-2020 13:14:12 (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
Sep-28-2020 13:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020 12:15	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-28-2020 13:14:12 (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-28-2020 13:14:12 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)

(b) (4), (b) (6)

7. Route:

Date	Location	User	Value	Reason
Sep-28-2020 13:14:12 (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-28-2020 13:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION 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-28-2020 13:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-31-2020 14:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 11:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-30-2020 05:08:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of blood sample collection date at visit 3.
Oct-29-2020 13:48:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/26/2020	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-27-2020 11:43:45 (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-27-2020 11:43:45 (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
Oct-27-2020 11:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 11:43:45 (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-27-2020 11:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/26/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-27-2020 11:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BL9S4P	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No 11291166

Subject Initials

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 11:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9S4P	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-27-2020 11:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9S4R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 11:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9S4R	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 11:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR6XTM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 11:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR6XTM	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-27-2020 11:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR6XTN	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (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:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials**

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

**Generated Time (GMT):** 29-Mar-2021 11:25

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-27-2020 11:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR6XTN	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-27-2020 11:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR6XTP	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-27-2020 11:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR6XTP	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Oct-30-2020 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/26/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-30-2020 11:47:00 (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
Oct-30-2020 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)



Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Mar-02-2021 05:48:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB updated
Feb-26-2021 02:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON: Please confirm if follow up SAE form was sent indicating the date of death update to 03Feb2021
Feb-21-2021 08:04:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Pending SDB update
Feb-19-2021 10:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE follow up to be filed. Date of death is 03Feb2021 per Death Certificate
Feb-19-2021 02:20:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON: Date of death till reported as 2021 in SDB.Please confirm the correct date of death, if already available
Feb-15-2021 04:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Pending Clinical review
Feb-12-2021 16:09:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	05Feb2021 date site was updated on subjects death, no confirmed date of death, subject found dead 03Feb2021. Cannot enter only 2021 in EDC

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1129**Subject No:** 11291166**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-12-2021 11:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON1: AER#2021124008, the date of death was reported as "2021" in Safety database but the full date is recorded as 03Feb2021 in AE CRF. Please confirm correct date of death. If safety update is required, please submit a follow-up form.
Feb-11-2021 14:29:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-11-2021 14:29:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Transcription Error
Feb-10-2021 04:31:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021124008, the date of death was reported as 15Jun2021 in Safety database but recorded as 05Feb2021 in AE CRF. Please confirm correct date of death. If safety update is required, please submit a follow-up form.
Feb-09-2021 12:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-09-2021 12:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

3. Status:

Date	Location	User	Value	Reason
Feb-19-2021 10:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-18-2021 13:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Response to 'Status' is 'Death' on Disposition- Folow up, but 'Death' CRF is not yet initiated. Please review and update as appropriate.
Feb-09-2021 12:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 12:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is DEATH but "Specify Status" is Provided.
Feb-09-2021 12:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DEATH	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Feb-09-2021 12:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-09-2021 12:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> date site was updated on subjects death, no confirmed date of death , subject found dead 03Feb2021	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Category:**

Date	Location	User	Value	Reason
Feb-05-2021 17:28:32 (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
Feb-05-2021 17:28:32 (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
Feb-28-2021 11:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Clo sed	Response satisfies query
Feb-24-2021 01:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Clo sed	Response satisfies query
Feb-23-2021 14:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: An swere d	New Information
Feb-23-2021 14:46:38 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	auto query (autoquery)	Query 3: An swere d	New Information

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

Canada)				
Feb-23-2021 14:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : myoc ardial infarct ion	New Information
Feb-23-2021 11:20:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Clo sed	Thanks
Feb-23-2021 11:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Rei ssued: Opene d	Thanks for confirming. Please provide a future date for a FUp so I can close the query. Thanks.
Feb-21-2021 20:59:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	SAE RECON: AER#2021124008,the term was updated to 'Myocardial infarction' in Safety database while recorded as 'death of unknown cause' in AE CRF. Please confirm correct term.If safety update is required, please submit a follow-up form.
Feb-16-2021 10:59:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swere d	PCP contacted, Certificate of death as well as other relevant records requested.
Feb-16-2021 10:58:15	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: An	PCP contacted and requested medical

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**Header Text:** c4591001

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-05:00) Eastern Time (US & Canada)			swere d	records as well as Certificate of Death
Feb-12-2021 08:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Op ened	CLINICAL_ Pls make every effort possible to obtain further information and provide a cause of death. Thanks
Feb-10-2021 17:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Op ened	Medical monitor_ Kindly provide further information/updates on the event, was the primary care physician contacted?. Thanks
Feb-09-2021 03:32:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Feb-08-2021 17:34:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	fatal AE cause unknown, family is considering autopsy
Feb-05-2021 21:54:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7171290;This 'Adverse Event' contains the term DEATH. If known, please provide the cause of death as the AE term with an outcome of FATAL or clarify.
Feb-05-2021 17:28:32 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Eastern Time (US & Canada)			death of unk nown cause
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4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 11:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021 UNK:UNK	New Information
Feb-25-2021 10:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Closed	GPD Clin: Query closed post review of SAE narrative.
Feb-25-2021 09:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Opened	GPD Clin: Please add the date of diagnosis or signs/symptoms.
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 11:30:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/3/2021 UNK:UNK	New Information
Feb-25-2021 10:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Closed	GPD Clin: Query closed post review of the SAE narrative.
Feb-25-2021 09:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Opened	GPD Clin: Please add the end date.
Feb-09-2021 11:06:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:	Transcription Error

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Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

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Form Status: Data Complete, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

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			UNK/UNK/2021 UNK:UNK	
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-09-2021 17:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 11:05:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-09-2021 11:05:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry
Feb-08-2021 06:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Toxicity Grade" is missing. Kindly review and update.

**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
Feb-10-2021 03:52:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE death of unknown cause: Response to "Is the adverse event serious?" is 'Yes' but "Serious

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

				Adverse Event Number" is blank.
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>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 /incapacity?</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
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>NO</p>	Initial Entry

**9. Is this event related to study treatment:**

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Mar-12-2021 17:01:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-12-2021 09:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-12-2021 09:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatm ent(s), this event is due to:  OTHER  <i>If Other, specify:</i>  hyperlipidemia	Transcription Error
Mar-11-2021 18:15:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINQUERY: "ahyperlipidemia" is reported. Please clarify if this should be hyperlipidemia
Mar-11-2021 17:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-11-2021 17:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatm ent(s), this event is due to:  OTHER  <i>If Other, specify:</i>  ahyperlipidemia	Transcription Error
Mar-10-2021 02:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: based on the SAE report, please clarify if the causality should be updated to reflect the underlying condition

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1129**Subject No:** 11291166**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

				of hyperlipidemia and/or disease progression.
Mar-09-2021 09:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINQUERY: based on the SAE report, please clarify if the causality should be updated to reflect the underlying condition of hyperlipidemia and/or disease progression.
Feb-24-2021 11:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  acute myocardial infarction	Transcription Error
Feb-09-2021 17:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 11:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-09-2021 11:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Initial Entry
Feb-08-2021 06:33:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this event related to study

**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, Not Complete

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

				treatment" is missing. Kindly review and update.
--	--	--	--	--

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

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Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 10:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Clos ed	Close Auto Query
Feb-18-2021 13:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Ope ned	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.
Feb-10-2021 01:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clos ed	Response satisfies query
Feb-09-2021 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	Changed data per query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

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Feb-09-2021 12:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Clos ed	Close Auto Query
Feb-09-2021 11:06:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Clos ed	Close Auto Query
Feb-08-2021 01:07:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Ope ned	DMW7171292;The outcome of this AE is selected as FATAL, but there are no Disposition eCRFs with a 'Status' of DEATH. Please review and update as appropriate.
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	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.
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ope ned	For AE death of unknown cause: Response to "What was the outcome of this adverse event?" is 'Fatal' but "Is the adverse event still ongoing?" is

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**Header Text:** c4591001

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**Subject No:** 11291166

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

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**Form Status:** Data Complete, Not Complete

**Site Name:** (1129) Jacksonville Center for Clinical Research

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				marked 'Yes'.
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Feb-05-2021 17:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-10-2021 03:52:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021124008	Initial Entry

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**Header Text:** c4591001

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**Subject No:** 11291166

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

**Form:** MEDICATION ERROR - Audit Trail

**Form Status:**

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Jan-22-2021 14:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Form Deleted	Transcription Error
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Form Created	

Header Text: c4591001

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Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

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**1. Category:**

Date	Location	User	Value	Reason
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> MEDICATION ERROR	Initial Entry

**2. Medication Error (Type of Medication Error):**

Date	Location	User	Value	Reason
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	<b>Data Entry:</b> Potential Administration of Incorre ct Dosage	Initial Entry

**3. Start Date:**

Date	Location	User	Value	Reason
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**4. Is the medication error still ongoing?**

Date	Location	User	Value	Reason
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	<b>Data Entry:</b> NO End Date:  Sep/8/2020	Initial Entry

**5. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	<b>Data Entry:</b> NO ACTION TAKEN	Initial Entry

**6. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
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Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

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Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	<b>Data Entry:</b> NO	Initial Entry
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**7. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**8. Did the Medication Error cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**9. Was this medication error associated with any adverse events?**

Date	Location	User	Value	Reason
Jan-22-2021 13:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

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

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

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-22-2021 11:33:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Feb-22-2021 11:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 11:33:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-22-2021 11:33:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1129

**Subject No:** 11291166

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-22-2021 11:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/31/2020	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-22-2021 11:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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**Site No:** 1129

**Subject No:** 11291166

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

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

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

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject Initials:** ---

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***I. Date of Collection / Notification of Death:***

Date	Location	User	Value	Reason
Mar-09-2021 09:51:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Mar-09-2021 09:39:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	date is correct per "Date of Notification on the Death Details form should = 05-Feb-2021 (this is the date the site is notified of the death)" - Katie Puig
Mar-09-2021 09:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 03/Feb/2021. Please review and update as appropriate
Mar-09-2021 09:33:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	New Information
Mar-04-2021 04:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Data updated
Mar-03-2021 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Answer Auto Query
Mar-03-2021 16:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Transcription Error
Mar-03-2021	ACV0PFEINFP6000	Giselle Castillo	Query 3: Closed	Response satisfies query

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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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**Subject No:** 11291166

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

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

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07:09:58 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)		
Mar-02-2021 17:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Open ed	Please update as "Notification of Death" = date of death
Mar-02-2021 11:28:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	no autopsy performed. included in SAE FUP
Mar-02-2021 11:28:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	please note that date of death per death certificate was 03Feb2021 however site was not notified until 05Feb2021. please clarify if "Notification of Death" = date of death or date of site notification.
Feb-25-2021 18:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Open ed	If "no autopsy performed as of 9Feb2021", Pls submit a FU form so this information is included in the safety report. Thanks
Feb-25-2021 11:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Open ed	DM: Per CRF, Date of Collection / Notification of Death (5/Feb/2021) is greater than the Date of Completion/Discontinuation /Death on the Disposition form 03/Feb/2021. Please review both the dates and update CRF if needed. Else clarify in query response.
Feb-24-2021 18:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-24-2021 11:17:11 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Original value is correct

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**Header Text:** c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1129**Subject No:** 11291166**Generated By:** (b) (4)**Form:** DEATH DETAILS CODED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)				
Feb-24-2021 11:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 03/Feb/2021. Please review and update as appropriate
Feb-24-2021 11:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Feb-24-2021 11:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Feb-24-2021 11:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Feb/5/2021	Transcription Error
Feb-19-2021 18:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Reissued:Open ed	CLINQUERY: please clarify if the Date of Collection / Notification of Death should be updated to 05Feb2021. Per query response, "Subject found dead 3Feb2021 (unknown actual date of death) Site notified of death on 05Feb2021".
Feb-19-2021 14:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4) [REDACTED]	Query 3: Reissued:Open ed	Pls elaborate
Feb-19-2021 10:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Initial Entry
Feb-19-2021 10:45:43	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Feb/3/2021	Initial Entry

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**Site No:** 1129

**Subject No:** 11291166

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(UTC-05:00) Eastern Time (US & Canada)				
Feb-19-2021 10:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-18-2021 17:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINQUERY: please clarify if the Date of Collection / Notification of Death should be updated to 05Feb2021 and not unknown. Per query response, "Subject found dead 3Feb2021 (unknown actual date of death) Site notified of death on 05Feb2021".
Feb-18-2021 17:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 13:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry
Feb-18-2021 13:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Feb-18-2021 13:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-18-2021 13:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-17-2021 12:43:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	Per query response to clinical, "no autopsy performed as of 9Feb2021". Pls submit a FU form so

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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

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

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

				this information is included in the safety report. Thanks
Feb-16-2021 18:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: per response, "please advise, no autopsy performed as of 9Feb2021. Is unknown acceptable at this time?" Please update with "unknown".
Feb-15-2021 10:39:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-11-2021 16:31:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	see item comment on DISPOSITION FORM. Subject found dead 3Feb2021 (unknown actual date of death) Site notified of death on 05Feb2021. Please advise on entry.
Feb-11-2021 14:29:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 03/Feb/2021. Please review and update as appropriate
Feb-09-2021 15:07:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please advise, no autopsy performed as of 9Feb2021. Is unknown acceptable at this time?
Feb-09-2021 14:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please report cause of death.
Feb-09-2021 12:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

2.a

Date	Location	User	Value	Reason
Feb-19-2021 10:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cause of Dea PRIMARY CAUS th Status: E OF DEATH Cause of Dea Myocardial Infarc th: tion	Initial Entry

2.a Cause of Death Status:

Date	Location	User	Value	Reason
Feb-19-2021 10:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CAUSE OF DEATH	Initial Entry

2.a Cause of Death:

Date	Location	User	Value	Reason
Feb-19-2021 10:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Myocardial Infarction	Initial Entry

2.b

Date	Location	User	Value	Reason
Mar-08-2021 14:12:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cause of De SECONDARY C ath Status: AUSE OF DEAT H Cause of De Hyperlipidemia ath:	New Information (DELETED)
Feb-19-2021 10:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cause of De SECONDARY C ath Status: AUSE OF DEAT H Cause of De Hyperlipidemia ath:	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291166

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:25

**2.b Cause of Death Status:**

Date	Location	User	Value	Reason
Mar-08-2021 14:12:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>SECONDARY CAUSE OF DEATH</del>	New Information <b>(DELETED)</b>
Feb-19-2021 10:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SECONDARY CAUSE OF DEATH	Initial Entry

**2.b Cause of Death:**

Date	Location	User	Value	Reason
Mar-09-2021 08:28:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	to be addressed by CRA
Mar-08-2021 14:12:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hyperlipidemia	New Information <b>(DELETED)</b>
Mar-08-2021 14:12:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-04-2021 17:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify if Hyperlipidemia should be reported as a fatal AE that resulted in death. Note: Hyperlipidemia is reported as a CAUSE OF DEATH.
Feb-19-2021 10:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hyperlipidemia	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291166

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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**1. Subject Status**

Date	Location	User	Value	Reason
Feb-09-2021 12:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-30-2020 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-08-2020 15:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-08-2020 14:18:42 (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
Feb-11-2021 14:29:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/3/2021	Transcription Error
Feb-09-2021 12:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/5/2021	Initial Entry
Oct-30-2020 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/26/2020	Initial Entry
Sep-08-2020 15:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/8/2020	Initial Entry
Sep-08-2020 14:18:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

090177e196ae30af\Final\Final On: 01-Apr-2021 04:13 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1129

**Site Name:** (1129) Jacksonville Center for Clinical Research

**Subject No:** 11291166

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:25

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-02-2020 11:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry