

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: COHORT_SELECTION

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](#)

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: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/4/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11291046]
2.	Birth Date:	(b) (6)/1950
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:	

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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	Aug/4/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1129

Subject No: 11291046

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 _____
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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	Aug/4/2020
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: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergy morphine]
	Start Date:	UNK/UNK/1974
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergy dilaudid]
	Start Date:	UNK/UNK/1974
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergy demerol]
	Start Date:	UNK/UNK/1974
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Food allergy]
	Start Date:	UNK/UNK/1971
	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: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergy]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gastroesophageal reflux disease]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diarrhea]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[abdominal hernia]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2004

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyperlipidemia]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[urination problems]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[endometriosis]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[overactive bladder]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[stress incontinence]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[excessive uterine bleeding related to endometriosis]
	Start Date:	UNK/UNK/1987
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[vitamin d deficiency]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypercalcemia]
	Start Date:	Apr/UNK/2018
	Ongoing:	NO End Date: Aug/UNK/2018

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cataracts]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[farsighted]
	Start Date:	UNK/UNK/1962
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[carpal tunnel syndrome left wrist]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2019
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sciatica]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[reactive airway]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[rosacea]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteoarthritis]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[back pain]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.y	Line/MH Number:	[25]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[fusion l5-s1]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.z	Line/MH Number:	[26]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[restless leg]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.aa	Line/MH Number:	[27]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left carpal tunnel syndrome]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2019
1.ab	Line/MH Number:	[28]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left knee torn meniscus]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.ac	Line/MH Number:	[29]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left knee torn meniscus repair]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.ad	Line/MH Number:	[30]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[type II diabetes]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.ae	Line/MH Number:	[31]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[high cholesterol]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.af	Line/MH Number:	[32]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[synovial cyst right popliteal space]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1129**Subject No:** 11291046**Generated By:** (b) (4)**Form:** GENERAL MEDICAL 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

1.ag	Line/MH Number:	[33]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[overweight]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.ah	Line/MH Number:	[34]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[high blood pressure]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.ai	Line/MH Number:	[35]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[multiple deep vein thrombosis]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2018
1.aj	Line/MH Number:	[36]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[multiple pulmonary embolisms]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2018

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.ak	Line/MH Number:	[37]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillitis]
	Start Date:	UNK/UNK/1953
	Ongoing:	NO End Date: UNK/UNK/1953
1.al	Line/MH Number:	[38]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillectomy]
	Start Date:	UNK/UNK/1953
	Ongoing:	YES
1.am	Line/MH Number:	[39]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[adenoidectomy]
	Start Date:	UNK/UNK/1971
	Ongoing:	NO End Date: UNK/UNK/1971
1.an	Line/MH Number:	[40]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hysterectomy]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.ao	Line/MH Number:	[41]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendicitis]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002
1.ap	Line/MH Number:	[42]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[abdominal hernia repairs]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2004
1.aq	Line/MH Number:	[43]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left meniscectomy]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

1.ar	Line/MH Number:	[44]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[carpal tunnel repair]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019
1.as	Line/MH Number:	[45]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[smoker]
	Start Date:	UNK/UNK/1969
	Ongoing:	NO End Date: UNK/UNK/1971
1.at	Line/MH Number:	[46]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tubal ligation]
	Start Date:	UNK/UNK/1984
	Ongoing:	YES

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1129

Subject No: 11291046

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:	Aug/4/2020
2.	Weight:	[201.0]
3.	Unit:	LB
4.	Height:	[62.75]
5.	Unit:	in
6.	Body Mass Index:	[35.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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:	Aug/4/2020
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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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 :	Aug/4/2020
2.	Randomization Number:	[222098]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**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: Aug/4/2020
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	[BP5PSH]
5.b	Sample ID	[BP5PSG]
5.c	Sample ID	[BP5PSF]
5.d	Sample ID	[BLD142]
5.e	Sample ID	[BLD143]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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: Aug/4/2020
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	[BP5PNP]
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291046

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:	Aug/4/2020 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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1129

Subject No: 11291046

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	---	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291046

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:	Aug/24/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[99.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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 _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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: Aug/24/2020
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	[BMB571]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291046

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:	Aug/24/2020 11:52
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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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	Sep/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/30/2020
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**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/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPC002]
5.b	Sample ID	[BPC003]
5.c	Sample ID	[BPC004]
5.d	Sample ID	[BLD192]
5.e	Sample ID	[BLD193]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Mar/1/2021
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V4_MONTH6_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**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: Mar/1/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BTZPJV]
5.b	Sample ID	[BTZPJW]
5.c	Sample ID	[BTZPJX]
5.d	Sample ID	[BSFMX1]
5.e	Sample ID	[BSFMX2]

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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: 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: 11291046

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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: 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: 11291046

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: 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: 11291046

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: 11291046

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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?	
----	--	--

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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: 11291046

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 Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** DATE OF VISIT
Sep/01/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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	Sep/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** UNPLANNED VISIT
Sep/01/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** CONTACT OUTCOME - UNPLANNED
Sep/01/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Sep/1/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[]

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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 :	Sep/21/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
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: 11291046

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: 11291046

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291046

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	Aneurysm x3 Mid lateral Cranial Artery	Jan/22/2021 UNK:UNK	NO End Date Time: Feb/9/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	right vocal cord paralysis	Jan/22/2021 UNK:UNK	YES	Repeating Pages

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1129
Subject No: 11291046
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Answered Queries, Verified
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)	[Aneurysm x3 Mid lateral Cranial Artery]
4.	Start Date Time:	Jan/22/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/9/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001		Form: ADVERSE EVENT REPORT
Visit: Logs - Unscheduled		Form Status: Data Complete, Answered Queries, Verified
Form Version: 22-Apr-2020 21:02		Site Name: (1129) Jacksonville Center for Clinical Research
Site No: 1129		Subject Initials: ---
Subject No: 11291046		Generated Time (GMT): 29-Mar-2021 11:25
Generated By: (b) (4)		
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown Etiology]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021211783]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[right vocal cord paralysis]
4.	Start Date Time:	Jan/22/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: MEDICATION ERROR

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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Medication Error

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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.						Repeating Pages

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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.	Date:	//

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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.						Repeating Pages

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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: 11291046

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 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: 11291046

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: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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:	

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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?	

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: 11291046

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: 11291046

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: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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	Feb/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/15/2021
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

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: 11291046

Subject Initials: ---

Generated By: (b) (4)

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: Feb/15/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSFMWG]
5.b	Sample ID	[BSFMWH]
5.c	Sample ID	[BTZPHN]
5.d	Sample ID	[BTZPHP]
5.e	Sample ID	[BTZPHR]

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**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: Feb/15/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BTZPKG]
-----	-----------	----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/25/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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	Feb/25/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	------------------------------	-------------

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/25/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[AA02936]
-----	-----------	-----------

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: 11291046

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/31/2020
2.	Erroneous Visit	

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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: TREATMENT UNBLINDED

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: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/6/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/21/2020

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: 11291046

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: 11291046

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
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Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 30-Jul-2020 21:29
Site No: 1129
Subject No: 11291046
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	Aug-06-2020 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291046

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	Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Alex Hill	N/A	Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Michael Koren	Approved	Jan-21-2021 18:09:17 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

(b) (6)	N/A	Jan-07-2021 08:41:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Michael Koren	Approved	Oct-14-2020 09:54:25 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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.

(b) (6)	N/A	Sep-21-2020 11:54:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Koren	Approved	Sep-11-2020 12:11:26 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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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.

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1129

Subject No: 11291046

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
Aug-04-2020 17:31:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:31:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-04-2020 17:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent O btained Aug/4/2020	Initial Entry

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1129**Subject No:** 11291046**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[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Aug-04-2020 17:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11291046	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1950	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-04-2020 17:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-04-2020 17:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1129

Subject No: 11291046

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

Aug-04-2020 17:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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
Aug-04-2020 17:32:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Aug-04-2020 17:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-04-2020 17:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-04-2020 17:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-04-2020 17:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: allergy morphine Start Date: UNK/UNK/1974 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: allergy morphine	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:34:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1974	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
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1.a Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-04-2020 17:34:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor allergy dila y Term: udid Start Date: UNK/UNK /1974 Ongoing: YES	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:34:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:34:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: allergy dilaudid	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:34:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1974	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:34:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-04-2020 17:35:45 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH Number: 3 Medical History Term: allergy de merol Start Date: UNK/UNK /1974 Ongoing: YES	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: allergy demerol	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1974	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-04-2020 17:36:56 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH Number: 4 Medical History Term: Food allergy Start Date: UNK/UNK /1971 Ongoing: YES	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Food allergy	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1971	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-04-2020 17:37:43 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH Number: 5 Medical History Term: seasonal allergy Start Date: UNK/UNK /1989 Ongoing: YES	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: seasonal allergy	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-04-2020 17:39:08 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH N 6 umber: Medical Hi story Term gastroesophage al reflux diseas : e Start Date: UNK/UNK/19 90 Ongoing: YES	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.f Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: gastroesophageal reflux di sease	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-04-2020 17:39:38 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH Number: 7 Medical History Term: diarrhea Start Date: UNK/UNK /2010 Ongoing: YES	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diarrhea	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.h

Date	Location	User	Value	Reason
Aug-04-2020 17:40:34 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH Number: 8 Medical History Term: abdominal hernia Start Date: UNK/UNK/2003 Ongoing: NO End Date: UNK/UNK/2004	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: abdominal hernia	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2003	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2004	Initial Entry

1.i

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 17:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 9 ber: Medical Histor hyperlipide y Term: mia Start Date: UNK/UNK /2000 Ongoing: YES	Initial Entry
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hyperlipidemia	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-04-2020 17:41:49 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)

Line/MH Number: 10

Medical History Term: urination problems

Start Date: UNK/UNK/2014

Ongoing: YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: urination problems	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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l.k

Date	Location	User	Value	Reason
Aug-04-2020 17:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: endometriosis Start Date: UNK/UNK/ 1989 Ongoing: NO End Date: UNK/UNK/1989	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: endometriosis	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1989	Initial Entry

1.l

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 17:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 12 ber: Medical History Term: overactive bladder Start Date: UNK/UNK /2015 Ongoing: YES	Initial Entry
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Aug-04-2020 17:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: overactive bladder	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-04-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

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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

17:43:44 (UTC-05:00) Eastern Time (US & Canada)	(autocalc)	Line/MH Number: 13 Medical History Term: stress incontinence Start Date: UNK/UNK/2015 Ongoing: YES
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: stress incontinence	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.n

Date	Location	User	Value	Reason
Aug-07-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

<p>12:34:14 (UTC-05:00) Eastern Time (US & Canada)</p>		<p>(b) (4), (b) (6)</p>	<p>Line/MH Number: 14 Medical History Term: excessive uterine bleeding related to endometriosis Start Date: UNK/UNK/1987 Ongoing: YES</p>	<p>Information</p>
<p>Aug-04-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH Number: 14 Medical History Term: excessive uterine bleeding Start Date: UNK/UNK/1987 Ongoing: YES</p>	<p>Initial Entry</p>

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

In Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

In Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 08:07:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-07-2020 12:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: excessive uterine bleeding related to endometriosis	Changed Information
Aug-07-2020 12:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is a symptom of endometriosis, log line 11. This log line will be inactivated.
Aug-06-2020 21:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please can you confirm if there is a diagnosis available for the following medhx:excessive uterine bleeding
Aug-04-2020 17:44:26	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: excessive uterine bleeding	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	ng	
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1.n Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1987	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Aug-04-2020 17:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 15 mber: Medical Histo vitamin d de ry Term: ficiency Start Date: UNK/UNK/ 2017 Ongoing: YES	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***L.o Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

L.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vitamin d deficiency	Initial Entry

L.o Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

L.o Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

L.p

Date	Location	User	Value	Reason
Aug-04-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

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Subject Initials: ---

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

17:45:40
(UTC-05:00) Eastern
Time (US & Canada)

(autocalc)

Line/MH Nu 16
mber:

Medical Histo hypercalcem
ry Term: ia

Start Date: Apr/UNK/2
018

Ongoing: NO

End Date:

Aug/UN
K/2018

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

L.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

L.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypercalcemia	Initial Entry

L.p Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2018	Initial Entry

L.p Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Aug/UNK/2018	Initial Entry

L.q

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 17:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 17 ber: Medical Histor cataracts y Term: Start Date: UNK/UN K/2019 Ongoing: YES	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cataracts	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.r

Date	Location	User	Value	Reason
Aug-04-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

17:46:49 (UTC-05:00) Eastern Time (US & Canada)	(autocalc)	Line/MH Number: 18 Medical History Term: farsighted Start Date: UNK/UNK/1962 Ongoing: YES
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***L.r Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

L.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: farsighted	Initial Entry

L.r Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1962	Initial Entry

L.r Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

L.s

Date	Location	User	Value	Reason
Aug-04-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

<p>17:49:18 (UTC-05:00) Eastern Time (US & Canada)</p>		<p>(b) (4), (b) (6)</p>	<p>Line/M 19 H Number: Medical History Term: carpal tunnel syndrome left wrist Start Date: UNK/UNK/2017 Ongoing: NO : End Date: UNK/UNK/2019</p>	<p>Error</p>
<p>Aug-04-2020 17:47:56 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/M 19 H Number: Medical History Term: carpal tunnel syndrome left wrist Start Date: UNK/UNK/2017 Ongoing: NO : End Date: UNK/UNK/1999</p>	<p>Initial Entry</p>

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: carpal tunnel syndrome le ft wrist	Initial Entry

1.s Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I.s Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-04-2020 17:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Transcription Error
Aug-04-2020 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Term carpal tunnel syndrome left wrist End Date is prior to Start Date.
Aug-04-2020 17:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

I.t

Date	Location	User	Value	Reason
Aug-04-2020 17:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 20 Medical History Term: sciatica Start Date: UNK/UNK/2017	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Ongoing: NO	
			End Date:	
			UNK/UN	
			K/2017	

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.t Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sciatica	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

1.u

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 17:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 21 ber: Medical Histor reactive air y Term: way Start Date: UNK/UNK /2016 Ongoing: YES	Initial Entry
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.u Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

I.u Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: reactive airway	Initial Entry

I.u Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.u Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.v

Date	Location	User	Value	Reason
Aug-04-2020 17:50:51 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)

Line/MH Number: 22

Medical History Term: rosacea

Start Date: UNK/UNK /1989

Ongoing: YES

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.v Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:50:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

I.v Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:50:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: rosacea	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:50:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:50:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.w

Date	Location	User	Value	Reason
Aug-04-2020 17:51:27 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)

Line/MH Number: 23

Medical History Term: osteoarthritis

Start Date: UNK/UNK /2019

Ongoing: YES

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.w Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

I.w Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: osteoarthritis	Initial Entry

I.w Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.w Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.x

Date	Location	User	Value	Reason
Aug-04-2020 17:52:07 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH Number: 24 Medical History Term: back pain Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017	
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.x Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24	Initial Entry

I.x Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: back pain	Initial Entry

I.x Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.x Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

I.y

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-04-2020 17:52:56 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocale)</p>	<p>Data Entry: Line/MH Number: 25 Medical History Term: fusion l5-s1 Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017</p>	<p>Initial Entry</p>
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.y Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25	Initial Entry

I.y Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fusion 15-s1	Initial Entry

I.y Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.y Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

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Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 17:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 26 ber: Medical Histor restless leg y Term: Start Date: UNK/UNK /2000 Ongoing: YES	Initial Entry
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**1.z Line/MH Number:**

Date	Location	User	Value	Reason
Aug-04-2020 17:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: restless leg	Initial Entry

1.z Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.z Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.aa

Date	Location	User	Value	Reason
Aug-05-2020 06:31:54	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1129
Site Name: (1129) Jacksonville Center for Clinical Research
Subject No: 11291046
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:25

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Line/MH Number: 27 Medical History Term: left carpal tunnel syndrome Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2019	
Aug-04-2020 17:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: N 27 Medical History Term: left carpal tunnel Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2019	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.aa Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 07:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-05-2020 06:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-05-2020 06:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : left carpal tunnel syndrome	Transcription Error
Aug-04-2020 18:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify LEFT CARPAL TUNNEL as follows...this is site only. If

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

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Generated By: (b) (4)

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

Canada)				reporting syndrome or decompression surgery, edit. Otherwise, clarify. Thank you.
Aug-04-2020 17:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : : left carpal tunnel	Initial Entry

1.aa Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.aa Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

1.ab

Date	Location	User	Value	Reason
Aug-04-2020 17:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 28	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Canada)			Medical History Term: left knee torn meniscus	
			Start Date: UNK/UNK/2005	
			Ongoing: NO	
			End Date:	
			UNK/UNK/2005	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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1.ab Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: left knee torn meniscus	Initial Entry

1.ab Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.ab Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

1.ac

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 17:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH N umber: 29 Medical Hi story Term : left knee torn m eniscus repair Start Date: UNK/UNK/200 5 Ongoing: NO End Date: UNK/UNK/ 2005	Initial Entry
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.ac Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29	Initial Entry

I.ac Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-04-2020 17:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: left knee torn meniscus re pair	Initial Entry

I.ac Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.ac Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

I.ad

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Aug-04-2020 17:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 30 ber: Medical Histor type II diab y Term: etes Start Date: UNK/UNK /2018 Ongoing: YES	Initial Entry
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.ad Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: type II diabetes	Initial Entry

1.ad Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.ad Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:56:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ae

Date	Location	User	Value	Reason
Aug-04-2020 17:57:07 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

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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

Eastern Time (US & Canada)			Line/MH Number: 31 Medical History Term: high cholesterol Start Date: UNK/UNK/2000 Ongoing: YES	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.ae Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:57:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:57:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: high cholesterol	Initial Entry

1.ae Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:57:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.ae Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:57:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.af

Date	Location	User	Value	Reason
Aug-04-2020 17:58:06 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH 32 Number: Medical History Term: synovial cyst right popliteal space Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2016	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.af Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: synovial cyst right poplite al space	Initial Entry

1.af Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.af Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

1.ag

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

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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

Aug-04-2020 17:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 33 ber: Medical History Term: overweight Start Date: UNK/UNK /2000 Ongoing: YES	Initial Entry
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.ag Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: overweight	Initial Entry

1.ag Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.ag Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ah

Date	Location	User	Value	Reason
Aug-04-2020 17:59:01 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Eastern Time (US & Canada)

Line/MH Number: 34

Medical History Term: high blood pressure

Start Date: UNK/UNK/1995

Ongoing: YES

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.ah Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 17:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 34	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: high blood pressure	Initial Entry

1.ah Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 17:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

1.ah Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ai

Date	Location	User	Value	Reason
Aug-04-2020 18:01:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

Header Text: c4591001 Visit: V1_DAY1_VAX1_L Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified Site No: 1129 Site Name: (1129) Jacksonville Center for Clinical Research Subject No: 11291046 Subject Initials: --- Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:25				
(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Line/MH 35 Number: Medical History Term: multiple deep vein thrombosis Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2018	
Aug-04-2020 17:59:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 35 Number: Medical History Term: multiple deep vein thrombosis Start Date: UNK/UNK/2018 Ongoing: NO End Date: UNK/UNK/2018	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.ai Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 17:59:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:59:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: multiple deep vein thrombosis	Initial Entry

1.ai Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:01:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Transcription Error
Aug-04-2020 17:59:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.ai Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 17:59:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

			UNK/UNK/2018	
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1.aj

Date	Location	User	Value	Reason
Aug-04-2020 18:01:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 36 Number: Medical Hi multiple pulmo story Term nary embolisms : Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/ 2018	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.aj Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 18:01:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 36	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:01:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: multiple pulmonary embolisms	Initial Entry

1.aj Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:01:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.aj Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:01:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

1.ak

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

Aug-04-2020 18:02:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 37 Medical History Term: tonsillitis Start Date: UNK/UNK/1953 Ongoing: NO End Date: UNK/UNK/1953	Initial Entry
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1.ak Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 18:02:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 37	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:02:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tonsillitis	Initial Entry

1.ak Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:02:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1953	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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I.ak Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:02:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1953	Initial Entry

I.al

Date	Location	User	Value	Reason
Aug-04-2020 18:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 38 ber: Medical Histor tonsillecto y Term: my Start Date: UNK/UNK /1953 Ongoing: YES	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**1.al Line/MH Number:**

Date	Location	User	Value	Reason
Aug-04-2020 18:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 38	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tonsillectomy	Initial Entry

1.al Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1953	Initial Entry

1.al Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.am

Date	Location	User	Value	Reason
Aug-04-2020 18:04:16 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			Line/MH Number: 39 Medical History Term: adenoidectomy Start Date: UNK/UNK/1971 Ongoing: NO End Date: UNK/UNK/1971	
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.am Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 18:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 39	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: adenoidectomy	Initial Entry

1.am Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1971	Initial Entry

1.am Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1971	Initial Entry

1.an

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 18:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 40 mber: Medical Hist hysterectomy ory Term: Start Date: UNK/UNK/1 989 Ongoing: NO End Date: UNK/UN K/1989	Initial Entry
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.an Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 18:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 40	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hysterectomy	Initial Entry

1.an Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

1.an Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1989	Initial Entry

1.ao

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 18:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 41 mber: Medical Hist appendicitis ory Term: Start Date: UNK/UNK/2 002 Ongoing: NO End Date: UNK/UN K/2002	Initial Entry
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.ao Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 18:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 41	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: appendicitis	Initial Entry

1.ao Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2002	Initial Entry

1.ao Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2002	Initial Entry

1.ap

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 18:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH N 42 umber: Medical His abdominal her tory Term: nia repairs Start Date: UNK/UNK/20 01 Ongoing: NO End Date: UNK/UNK /2004	Initial Entry
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.ap Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 18:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 42	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: abdominal hernia repairs	Initial Entry

1.ap Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2001	Initial Entry

1.ap Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2004	Initial Entry

1.aq

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-04-2020 18:08:17 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocale)</p>	<p>Data Entry: Line/MH Nu 43 mber: Medical Hist left meniscec ory Term: tomy Start Date: UNK/UNK/2 005 Ongoing: NO End Date: UNK/UN K/2005</p>	<p>Initial Entry</p>
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.aq Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 18:08:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 43	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:08:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: left meniscectomy	Initial Entry

1.aq Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:08:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.aq Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:08:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

1.ar

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Aug-04-2020 18:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: Line/MH Nu 44 mber: Medical Hist carpal tunnel ory Term: repair Start Date: UNK/UNK/2 019 Ongoing: NO End Date: UNK/UN K/2019	Initial Entry
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.ar Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 18:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 44	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: carpal tunnel repair	Initial Entry

1.ar Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.ar Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

1.as

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

<p>Aug-04-2020 18:09:32 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocale)</p>	<p>Data Entry: Line/MH Number: 45 Medical History Term: smoker Start Date: UNK/UNK/1969 Ongoing: NO End Date: UNK/UNK/1971</p>	<p>Initial Entry</p>
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***1.as Line/MH Number:***

Date	Location	User	Value	Reason
Aug-04-2020 18:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 45	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: smoker	Initial Entry

1.as Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1969	Initial Entry

1.as Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1971	Initial Entry

1.at

Date	Location	User	Value	Reason
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Header Text: c4591001

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Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Aug-04-2020 18:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 46 ber: Medical Histor tubal ligati y Term: on Start Date: UNK/UNK /1984 Ongoing: YES	Initial Entry
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

1.at Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 18:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 46	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tubal ligation	Initial Entry

1.at Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1984	Initial Entry

1.at Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 18:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Aug-04-2020 18:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-04-2020 18:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 201.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 62.75	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1129

Subject No: 11291046

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

Aug-04-2020 18:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry
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6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.9	Initial Entry
Aug-04-2020 18:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-04-2020 18:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 99.4 Temperature Unit: Temperature Location: ORAL C AVITY	Initial Entry
Aug-04-2020 18:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: Temperature Unit: Temperature Location:	Initial Entry

7.a Record Identifier:

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-04-2020 18:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Aug-05-2020 08:19:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-05-2020 08:19:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-05-2020 08:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-05-2020 08:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Transcription Error
Aug-05-2020 08:19:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection Date 05/Aug/2020 is not the same as the Date of Visit 04/Aug/2020.

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical Research
Subject No: 11291046 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

				Please correct or confirm.
Aug-05-2020 08:19:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/5/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-05-2020 08:19:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-05-2020 08:19:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-04-2020 18:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-De 113 fined Identi fier: Test:: Choriogonado tropin Beta_P X113 Result:: Not Done:: NOT DONE	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical Research
Subject No: 11291046 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta _PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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
Aug-04-2020 18:11:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-04-2020 18:11:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 222098	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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
Aug-04-2020 18:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-04-2020 18:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-04-2020 19:40:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-04-2020 18:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-04-2020 18:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Canada)			Aug/4/2020	
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5.a

Date	Location	User	Value	Reason
Aug-04-2020 19:40:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5PSH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 19:40:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PSH	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-04-2020 19:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5PSG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 19:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PSG	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Aug-04-2020 19:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5PSF	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 19:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PSF	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-04-2020 19:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLD142	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 19:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD142	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-04-2020 19:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLD143	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

5.e Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 19:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD143	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Aug-04-2020 18:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-04-2020 18:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-04-2020 19:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-04-2020 18:11:59 (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.
Aug-04-2020 18:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Canada)			Aug/4/2020	
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5.a

Date	Location	User	Value	Reason
Aug-04-2020 19:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5PNP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 19:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PNP	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291046

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
Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020 12:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291046

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

Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 18:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1129

Subject No: 11291046

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
Aug-04-2020 18:12:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICI TY E-DIARY COLLECT ED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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
Aug-28-2020 05:10:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-27-2020 11:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-27-2020 05:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please consider to update missing details on Vaccination form. Thank you.
Aug-24-2020 13:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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2.b

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or syste NO mic symptoms prese nt on the last day the Subject Diary was c ompleted?:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE MUSCL E PAIN Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER M USCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENER JOINT PAIN Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JO INT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT IN JECTI ON SI TE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SIT E	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291046

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
Aug-24-2020 15:52:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-24-2020 15:52:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identif 1 ier:: Temperature: 99.5 Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.5	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291046

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 Unit:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 15:52:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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6.a

Date	Location	User	Value	Reason
Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Define Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
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Header Text: c4591001
Visit: V2_VAX2_L **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical Research
Subject No: 11291046 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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6.a Not Done:

Date	Location	User	Value	Reason
Aug-24-2020 15:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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
Aug-27-2020 10:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 10:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 11:00:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 10:59:48 (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.
Aug-27-2020 10:59:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)			Aug/24/2020	
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5.a

Date	Location	User	Value	Reason
Aug-27-2020 11:00:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMB571	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 11:00:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMB571	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291046

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020 11:52	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291046

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

Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 15:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Nov-11-2020 17:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-11-2020 09:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	confirmed seasonal allergies per investigator note
Nov-11-2020 02:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	RQ1: Response states 'investigator discretion attributed to seasonal allergies(historic)'. Please confirm if Illness ed diary entry on 12Oct2020 was deemed erroneous and that subject had no Covid Illness symptoms.
Nov-10-2020 16:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	investigator discretion attributed to seasonal allergies(historic)
Nov-10-2020 15:39:36 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Illness eDiary: Subject reported "Yes" for the

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1129**Subject No:** 11291046**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

Eastern Time (US & Canada)		(b) (4), (b) (6)		question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 12Oct2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-30-2020 07:16:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation
Sep-29-2020 11:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject contacted 1Sep2020, no visit or swab needed per investigator.
Sep-29-2020 10:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 31AUG2020. But there is no COVID Illness visit reported in the database. Please

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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

				clarify.
Sep-21-2020 11:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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2.b

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical Research
Subject No: 11291046 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRH EA Were fever or sy YES stemic symptom Ongoin s present on the g? last day the Sub ject Diary was c NO ompleted?: Stop Date : Au g/3 0/2 02 0	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/30/2020	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE MUSCL E PAIN Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD M USCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT PAIN Were fever or sy NO stemic symptoms present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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2.h Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JO INT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reacti RE	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291046**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)			on::	DN ES S	
			Were injection site re actions present on th e last day the Subjec t Diary was complete d?:	NO	

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reacti on:: SW ELL ING Were injection site r eactions present on t he last day the Subj ect Diary was compl eted?:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

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Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT IN JECTI ON SI TE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SIT E	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-21-2020 15:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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-23-2020 17:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 17:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 17:10:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 17:10:30 (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-23-2020 17:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

Subject Initials: ---

Generated By: (b) (4)

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5.a

Date	Location	User	Value	Reason
Sep-23-2020 17:10:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPC002	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 17:10:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC002	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-23-2020 17:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPC003	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 17:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC003	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-23-2020 17:10:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Sample ID: BPC004	
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5.c Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 17:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC004	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-23-2020 17:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLD192	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 17:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD192	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-23-2020 17:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLD193	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.e Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 17:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD193	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: DATE OF VISIT - 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. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 11291046

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
Mar-03-2021 13:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-03-2021 13:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 13:54:05 (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.
Mar-03-2021 13:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Mar-03-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BTZPJV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPJV	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 13:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BTZPJW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPJW	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 13:54:40	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Sample ID: BTZPJX	
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5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPJX	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-03-2021 13:54:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFMX1	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:54:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFMX1	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-03-2021 13:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFMX2	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.e Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFMX2	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** DATE OF VISIT - eCRF Audit Trail History
Sep/01/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Sep-01-2020 15:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Transcription Error
Sep-01-2020 14:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on **Form:** UNPLANNED VISIT - eCRF Audit Trail History
Sep/01/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Sep-01-2020 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 14:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-01-2020 14:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/01/2020 **Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

Date	Location	User	Value	Reason
Sep-01-2020 14:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Sep-01-2020 15:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-01-2020 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Contact 01/Sep/2020 is not equal to the Date of Visit 31/Aug/2020 within same unplanned visit. Please review and update as appropriate.
Sep-01-2020 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-01-2020 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Sep/1/2020	Transcription Error

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/01/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

			Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	
Sep-01-2020 14:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Sep-01-2020 14:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-22-2020 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-22-2020 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-22-2020 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (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: 11291046

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-12-2021 16:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Query 1: Answered	Thank you for confirming that you had read that and still issued the query for that exact information. If there is anything else you need copied into the query history, please let me know.
Mar-12-2021 14:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Open ed	Thank you for confirming... I have read the updated report and this information has not been added to safety

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

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				report yet. To clarify with DSU.
Mar-12-2021 14:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Query 1: Answered	Thank you for the prompt query. Could you please clarify why you didn't read the updated report prior to firing query? Per update submitted 09MAR2021: "Aneurysm found on CT scan done 22JAN2021 to evaluate RIGHT VOCAL CORD PARALYSIS starting 19JAN2021.
Mar-12-2021 14:10:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for the prompt response. Could you please clarify if diagnosis was made on screening or subject had any neurological symptoms/signs that prompted the visit to PCP?
Mar-11-2021 11:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Query 1: Answered	Follow up report submitted 09MAR2021
Mar-10-2021 11:46:50 (UTC-05:00) Eastern	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Have you provided information on

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1129**Subject No:** 11291046**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries, Verified**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)				1]symptoms of onset, 2]workup, 3]treatment for this SAE in the FU? Thanks
Mar-09-2021 17:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No lumbar puncture occurred, transcription error in SAE FUP, new SAE FUP submitted with correction
Mar-05-2021 05:50:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Medical Monitor_ Pls provide additional information on clinical course: 1]symptoms of onset, 2]workup, 3]treatment) and 4] indication for lumbar puncture. Thanks
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Aneurysm x3 Mid lateral Cranial Artery	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Jan/22/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

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Generated By: (b) (4)

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Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: NO End Date Time: Feb/9/2021 UNK:UNK	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-01-2021 04:13:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-26-2021 09:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE now reported to Safety database
Feb-18-2021 02:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Aneurysm x3 Mid lateral Cranial Artery(Onset date:22Jan2021) is not reported to Safety database but marked serious

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Verified

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Subject Initials: ---

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				on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Feb-17-2021 01:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Aneurysm x3 Mid lateral Cranial Artery: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1129**Subject No:** 11291046**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries, Verified**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

			<p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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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-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1129

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Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

			Unknown Etiology	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: NO	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-01-2021 04:12:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021211783	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 13:35:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical: site will update when records available.
Mar-08-2021 13:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	additional records requested
Mar-08-2021 11:33:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: how was diagnosis made? pls advise if this was an acute event or if subject had prior symptoms to actual diagnosis.

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

				Thanks
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right vocal cord paralysis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	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-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-26-2021 15:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-26-2021 13:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-26-2021 13:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study t reatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Transcription Error

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

			unknown etiology	
Feb-19-2021 12:39:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise why assessed as 'related' when AE start is months after last vaccination. Is it related to AE of aneurysm with same start date? Thanks
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291046

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

Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 14:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

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: 11291046

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-17-2021 14:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/15/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - 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. Consent Was:

Date	Location	User	Value	Reason
Feb-17-2021 14:25:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/15/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Feb-19-2021 14:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-19-2021 14:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-19-2021 14:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 14:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-19-2021 14:14:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/15/2021	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Feb-19-2021 14:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFMWG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 14:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFMWG	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-19-2021 14:15:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFMWH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 14:15:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFMWH	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-19-2021 14:15:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001
Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
 Unscheduled
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical Research
Subject No: 11291046 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Sample ID: BTZPHN
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5.c Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 14:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPHN	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-19-2021 14:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BTZPHP	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 14:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPHP	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-19-2021 14:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BTZPHR	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

5.e Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 14:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPHR	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Feb-19-2021 14:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-19-2021 14:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-19-2021 14:16:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 14:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-19-2021 14:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/15/2021	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001
Visit: V201_SURVEIL_CONSENT - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1129
Subject No: 11291046
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a

Date	Location	User	Value	Reason
Feb-19-2021 14:16:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BTZPKG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 14:16:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPKG	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/25/2021

Form: DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE
- eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

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
Mar-11-2021 17:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/25/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Mar-11-2021 17:15:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SSWAB_WEEK2	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/25/2021

Form Version: 10-Oct-2020 15:57

Site No: 1129

Subject No: 11291046

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
- 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. Data Origin

Date	Location	User	Value	Reason
Mar-11-2021 17:16:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-11-2021 17:16:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-11-2021 17:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 17:16:23 (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.
Mar-11-2021 17:16:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001
Visit: V202_SURVEIL_SWAB 1 -
 - Unscheduled Visit on Feb/25/2021
Form Version: 10-Oct-2020 15:57
Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
 - eCRF Audit Trail History
Site No: 1129
Form Status: Data Complete, Verified
Site Name: (1129) Jacksonville Center for Clinical Research
Subject No: 11291046
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:25

			Feb/25/2021	
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5.a

Date	Location	User	Value	Reason
Mar-11-2021 17:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: AA02936	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 17:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: AA02936	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

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: 11291046

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
Jan-07-2021 08:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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
Jan-07-2021 08:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 08:41:41 (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.
Jan-07-2021 08:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-07-2021 08:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-07-2021 08:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291046

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Sep-22-2020 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-04-2020 18:11:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZE D	Initial Entry
Aug-04-2020 17:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-12-2021 10:21:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 17:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-11-2021 15:50:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	HOLDS: For V202 the lab has received nasal self swab barcode AA02936; however, this barcode has not been recorded.

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291046

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

				Please review and update as appropriate. Otherwise please clarify.
Sep-22-2020 09:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry
Aug-04-2020 18:11:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/4/2020	Initial Entry
Aug-04-2020 17:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/4/2020	Initial Entry

090177e196ae30b9\Final\Final On: 01-Apr-2021 04:14 (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: 11291046

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
Sep-11-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry