

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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/7/2020
----	--------------	---

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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11291059]
2.	Birth Date:	(b) (6)/1943
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291059

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/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1129

Subject No: 11291059

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

090177e196ae30b6\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: 11291059

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/7/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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:	[levaquin allergy]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Non-organic fruit allergy]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/1960
	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: 11291059

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.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Pollen Allergy]
	Start Date:	UNK/UNK/1960
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Colon polyps]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Enlarged Prostate]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.g	Line/MH Number:	[7]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Erectile dysfunction]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Low libido]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Vitamin B12 deficiency]
	Start Date:	UNK/UNK/2010
	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: 11291059

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.j	Line/MH Number:	[10]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Bilateral Cataracts]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1999
1.k	Line/MH Number:	[11]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Myopia]
	Start Date:	UNK/UNK/1960
	Ongoing:	YES
1.1	Line/MH Number:	[12]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hyperopia]
	Start Date:	UNK/UNK/1990
	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: 11291059

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:	[Headaches]
	Start Date:	UNK/UNK/1960
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Left Carpal Tunnel Syndrome]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/2019
1.o	Line/MH Number:	[15]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Right Carpal Tunnel Syndrome]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.p	Line/MH Number:	[16]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[exercise induced asthma]
	Start Date:	UNK/UNK/1950
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Acne]
	Start Date:	UNK/UNK/1960
	Ongoing:	NO End Date: UNK/UNK/1965
1.r	Line/MH Number:	[18]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Eczema]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.s	Line/MH Number:	[19]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[basal cell carcinoma]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.t	Line/MH Number:	[20]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Osteoarthritis]
	Start Date:	Jul/UNK/2018
	Ongoing:	YES
1.u	Line/MH Number:	[21]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Type 2 Diabetes]
	Start Date:	UNK/UNK/1992
	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: 11291059

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.v	Line/MH Number:	[22]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hypercholesterolemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.w	Line/MH Number:	[23]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.x	Line/MH Number:	[24]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Cardiac catheterization]
	Start Date:	Jan/27/2020
	Ongoing:	NO End Date: Jan/27/2020

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291059

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:	[Stent placement left anterior descending artery]
	Start Date:	Jan/27/2020
	Ongoing:	NO End Date: Jan/27/2020
1.z	Line/MH Number:	[26]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.aa	Line/MH Number:	[27]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2005
	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: 11291059

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.ab	Line/MH Number:	[28]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Transurethral resection of the prostate]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013
1.ac	Line/MH Number:	[29]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Right total knee replacement]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.ad	Line/MH Number:	[30]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Bilateral Inguinal Hernia repair]
	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: 11291059

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.ae	Line/MH Number:	[31]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Bilateral Cataracts surgery]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1999
1.af	Line/MH Number:	[32]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Tonsillectomy]
	Start Date:	UNK/UNK/1965
	Ongoing:	NO End Date: UNK/UNK/1965
1.ag	Line/MH Number:	[33]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hemorrhoidectomy]
	Start Date:	UNK/UNK/1980
	Ongoing:	NO End Date: UNK/UNK/1980

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291059

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.ah	Line/MH Number:	[34]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hemorrhoidectomy]
	Start Date:	UNK/UNK/1995
	Ongoing:	NO End Date: UNK/UNK/1995
1.ai	Line/MH Number:	[35]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[right Shoulder reconstruction]
	Start Date:	UNK/UNK/1997
	Ongoing:	NO End Date: UNK/UNK/1997
1.aj	Line/MH Number:	[36]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Acid Reflux]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.ak	Line/MH Number:	[37]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[urination problems]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.al	Line/MH Number:	[38]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[right shoulder reconstruction]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.am	Line/MH Number:	[39]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[nocturia]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.an	Line/MH Number:	[40]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[tonsillitis]
	Start Date:	UNK/UNK/1965
	Ongoing:	NO End Date: UNK/UNK/1965

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/7/2020
2.	Weight:	[160.6]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[25.2]

Vital Signs Details

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

090177e196ae30b6\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: 11291059

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/7/2020
2.	Randomization Number:	[224051]
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: 11291059

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/7/2020
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	[BP5PWP]
5.b	Sample ID	[BP5PWR]
5.c	Sample ID	[BP5PWS]
5.d	Sample ID	[BLD1FD]
5.e	Sample ID	[BLD1FF]

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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: Aug/7/2020
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	[BP5PJL]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291059

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/7/2020 13:45
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

090177e196ae30b6\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: 11291059

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: 11291059

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/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1129

Subject No: 11291059

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

[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

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR 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

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b6\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: 11291059

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/28/2020
----	-------	-------------

Vital Signs Details

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

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BMB5F3]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291059

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/28/2020 11:58
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

090177e196ae30b6\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: 11291059 **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/25/2020
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: 11291059 **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

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR 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

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

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

090177e196ae30b6\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:** 11291059**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/25/2020
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	[BLD199]
5.b	Sample ID	[BLD198]
5.c	Sample ID	[BPC00H]
5.d	Sample ID	[BPC00J]
5.e	Sample ID	[BPC00K]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291059

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	Feb/19/2021
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: 11291059

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/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSFMY8]
5.b	Sample ID	[BSFMY9]
5.c	Sample ID	[BTZPN3]
5.d	Sample ID	[BTZPN4]
5.e	Sample ID	[BTZPN5]

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291059

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: 11291059

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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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059

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:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1129

Subject No: 11291059

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject Initials: ---

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

090177e196ae30b6\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: 11291059

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	[]
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090177e196ae30b6\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: 11291059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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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: 11291059

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?	
----	--	--

090177e196ae30b6\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: 11291059

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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical
Research**Subject No:** 11291059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical Research

Subject No: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Unplanned Assessments

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

Header Text: c4591001

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

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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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/25/2020
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: 11291059

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 **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059

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:	
----	-----------------------	--

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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	Left supraclavicular adenopathy	Aug/31/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	worsening hypertension	Jan/1/2021 08:00	YES	Repeating Pages

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[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)	[Left supraclavicular adenopathy]
4.	Start Date Time:	Aug/31/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1

090177e196ae30b6\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: 11291059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b6\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: 11291059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening hypertension]
4.	Start Date Time:	Jan/1/2021 08:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

090177e196ae30b6\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: 11291059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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
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

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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	[]

090177e196ae30b6\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: 11291059

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: 11291059

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

[Back to Form](#)

Medication Error

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

090177e196ae30b6\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: 11291059

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae30b6\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: 11291059

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae30b6\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: 11291059

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: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291059

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: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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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: 11291059

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: 11291059

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:	

090177e196ae30b6\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: 11291059

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?	

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059

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: 11291059

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 - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1. Consent Was:

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical
Research**Subject No:** 11291059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical
Research**Subject No:** 11291059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

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: 11291059 **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/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059 **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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/17/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291059

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: 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: 11291059

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:	[]

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291059

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/25/2020

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: 11291059

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: 11291059

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: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-07-2020 17:48:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-19-2021 11:57:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Michael Koren	Approved	Jan-21-2021 18:19:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

Affidavit:

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

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

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

(b) (6)	N/A	Dec-18-2020 13:39:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

Michael Koren	Approved	Nov-06-2020 09:28:44 (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	Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Koren	Approved	Oct-14-2020 10:00:03 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30b6\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: 11291059

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-25-2020 13:16:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Koren	Approved	Sep-11-2020 12:16:09 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291059

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Verified

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject Initials: ---

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.

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-07-2020 17:46:11 (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-07-2020 17:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30b6\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: 11291059

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-07-2020 17:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/7/2020	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1129

Subject No: 11291059

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-07-2020 17:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11291059	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-07-2020 17:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1943	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-07-2020 17:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:47:00 (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
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-07-2020 17:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30b6\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: 11291059

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-07-2020 17:47:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/7/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291059

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-07-2020 17:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-07-2020 17:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-07-2020 17:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30b6\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:** 11291059**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[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-07-2020 17:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 1 Medical History Term: levaquin allergy Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 17:51:15 (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-07-2020 17:51:15 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: levaquin allergy	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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 17:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 17:51:15 (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-07-2020 17:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Term: Non-organic fruit allergy	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

			Start Date UNK/UN : K/1990 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: 11291059

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-07-2020 17:52:02 (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-07-2020 17:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Non-organic fruit alle rgy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 17:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.c

Date	Location	User	Value	Reason
Aug-13-2020 17:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 3 H Num ber: Medical Gastroesop History hageal refl Term: ux disease Start Da UNK/UN te: K/1960 Ongoing YES :	Initial Entry
Aug-07-2020 17:54:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 3 H Num ber: Medical Gastroesop History hageal refl Term: ux disease Start Da te:	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

			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: 11291059

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-07-2020 17:54:01 (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-07-2020 17:54:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastroesophageal refl ux disease	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 17:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1960	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:54:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.d

Date	Location	User	Value	Reason
Aug-07-2020 17:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 4 Medical History Term: Pollen Allergy Start Date: UNK/UNK/1960 Ongoing: YES	Initial Entry

090177e196ae30b6\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: 11291059

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-07-2020 17:54:30 (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-07-2020 17:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pollen Allergy	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 17:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1960	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.e

Date	Location	User	Value	Reason
Aug-07-2020 17:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number: Medical History Term: Colon polys Start Date: UNK/UNK/2018 Ongoing: NO End Date: UNK/UNK/2018	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 17:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 17:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Colon polyps	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 17:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry
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If

Date	Location	User	Value	Reason
Aug-07-2020 17:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 6 umber: Medical His Enlarged tory Term: Prostate Start Date: UNK/U NK/2013 Ongoing: YES	Initial Entry

090177e196ae30b6\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: 11291059

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-07-2020 17:57:59 (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-07-2020 17:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Enlarged Prostate	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 17:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.g

Date	Location	User	Value	Reason
Aug-07-2020 17:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 7 Number: Medical History Term Erectile dysfunction Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae30b6\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: 11291059

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-07-2020 17:58:37 (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-07-2020 17:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erectile dysfunction	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 17:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.h

Date	Location	User	Value	Reason
Aug-07-2020 17:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 8 Medical History Term: Low library Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae30b6\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: 11291059

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-07-2020 17:59:19 (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-07-2020 17:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low libido	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 17:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.i

Date	Location	User	Value	Reason
Aug-07-2020 18:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9 Number: Medical History Term: Vitamin B 12 deficiency Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae30b6\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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Site No: 1129

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Subject No: 11291059

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-07-2020 18:00:18 (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-07-2020 18:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vitamin B12 deficiency	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 18:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 18:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I,j

Date	Location	User	Value	Reason
Aug-13-2020 17:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 10 Number: Medical History T Bilateral History T Cataracts erm: Start Date: UNK/ UNK/1990 Ongoing: NO End Date: UNK/ UNK/1 999	Initial Entry
Aug-07-2020 18:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 10 Number: Medical History T Bilateral History T Cataracts erm:	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Version: 22-Apr-2020 21:03

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

			Start Date: Ongoing: NO End Date: UNK/ UNK/1 999	
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1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 18:01:41 (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-07-2020 18:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilateral Cataracts	Initial Entry

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Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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1.j Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 17:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 18:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

1.k

Date	Location	User	Value	Reason
Aug-13-2020 17:30:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 11 Number: Medical H Myopia istory Ter m:	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

			Start Date UNK/U : NK/196 0 Ongoing: YES	
Aug-07-2020 18:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 11 Number: Medical H Myopia istory Ter m: Start Date UNK/U : NK/196 0 Ongoing:	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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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: 11291059

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-07-2020 18:03:42 (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-07-2020 18:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Myopia	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 18:03:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1960	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-13-2020 17:30:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.1

Date	Location	User	Value	Reason
Aug-13-2020 17:30:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 12 Number: Medical Hi Hypero story Term pia : Start Date: UNK/U NK/199 0 Ongoing: YES	Initial Entry
Aug-07-2020 18:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 12 Number: Medical Hi Hypero story Term pia : Start Date: UNK/U NK/199 0 Ongoing:	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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-07-2020 18:04:15 (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-07-2020 18:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperopia	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 18:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-13-2020 17:30:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.m

Date	Location	User	Value	Reason
Aug-07-2020 18:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 13 Medical History Term: Headaches Start Date: UNK/UNK/1960 Ongoing: YES	Initial Entry

090177e196ae30b6\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: 11291059

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-07-2020 18:04:42 (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-14-2020 04:08:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Closed	recurrent terms being discussed
Aug-12-2020 15:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Opened	Ongoing headache is listed with a start year of 1960. Please confirm if this is considered recurrent headache and update the medical history term as specified in the Case Report Form

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

				Guidelines.
Aug-07-2020 18:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headaches	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 18:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1960	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 18:04:42 (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 18:06:26 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 14	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

H Number:

Medical History Term: Left Carpal Tunnel Syndrome

Start Date: UNK/UNK/1990

Ongoing: NO
: End Date:

UNK/UNK/2019

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 18:06:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:06:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left Carpal Tunnel S yndrome	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 18:06:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 18:06:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry
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1.o

Date	Location	User	Value	Reason
Aug-07-2020 18:07:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 15 H Numb er: Medical Right Carpal History Tunnel Synd Term: rome Start Da UNK/UNK/ te: 2019 Ongoing NO : End Date: UNK/UN K/2019	Initial Entry

090177e196ae30b6\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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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 18:07:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:07:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right Carpal Tunnel Syndrome	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 18:07:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 18:07:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry
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1.p

Date	Location	User	Value	Reason
Aug-08-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 16 Number: Medical History Term: exercise in reduced asthma Start Date: UNK/UNK/1950 Ongoing: YES	Initial Entry

090177e196ae30b6\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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Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Aug-08-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: exercise induced asth ma	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1950	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.q

Date	Location	User	Value	Reason
Aug-08-2020 10:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 17 Number: Medical History Term: Acne Start Date UNK/UNK/1960 Ongoing: NO End Date : UNK/UNK/1965	Initial Entry

090177e196ae30b6\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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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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-08-2020 10:02:23 (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-08-2020 10:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acne	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1960	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

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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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1965	Initial Entry
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l.r

Date	Location	User	Value	Reason
Aug-08-2020 10:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 18 Medical History Term: Eczema Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae30b6\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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Generated Time (GMT): 29-Mar-2021 11:25

I.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 04:09:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Closed	no longer required
Aug-12-2020 14:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Opened	Please update medical history condition to specify body site/location of eczema as applicable.
Aug-08-2020 10:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eczema	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

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Subject No: 11291059

Subject Initials: ---

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

I.r Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Aug-08-2020 10:02:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.s

Date	Location	User	Value	Reason
Aug-08-2020 10:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 19 Number: Medical H basal cell c istory Ter arcinoma m: Start Date UNK/UN : K/2014	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

			Ongoing: NO	
			End Date	
			:	
			UNK/U	
			NK/201	
			4	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

Generated By: (b) (4)

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

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1.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:03:39 (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-08-2020 10:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: basal cell carcinoma	Initial Entry

1.s Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.s Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

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Generated By: (b) (4)

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

Aug-08-2020 10:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry
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1.t

Date	Location	User	Value	Reason
Aug-08-2020 10:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 20 Medical History Term: Osteoarthritis Start Date: Jul/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

1.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:04:16 (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-08-2020 10:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/UNK/2018	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:04:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.u

Date	Location	User	Value	Reason
Aug-08-2020 10:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 21 Medical History Term: Type 2 Diabetes Start Date: UNK/UNK/1992 Ongoing: YES	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.u Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

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

Date	Location	User	Value	Reason
Aug-08-2020 10:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type 2 Diabetes	Initial Entry

1.u Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1992	Initial Entry

1.u Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.v

Date	Location	User	Value	Reason
Aug-08-2020 10:08:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 22 Number: Medical History Term: hypercholia Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Version: 22-Apr-2020 21:03

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Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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-08-2020 10:08:58 (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-08-2020 10:08:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypercholesterolemia	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:08:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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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Site No: 1129

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:08:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.w

Date	Location	User	Value	Reason
Aug-08-2020 10:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 23 Medical History Term: Hypertension Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.w Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

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

Date	Location	User	Value	Reason
Aug-08-2020 10:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

1.w Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.w Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.x

Date	Location	User	Value	Reason
Aug-08-2020 10:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 24 Number: Medical History Term: Cardiac cat heterization Start Date: Jan/27/2020 Ongoing: NO End Date: Jan/27/2020	Initial Entry

090177e196ae30b6\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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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.x Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24	Initial Entry

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

Date	Location	User	Value	Reason
Aug-08-2020 10:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cardiac catheterization	Initial Entry

1.x Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2020	Initial Entry

1.x Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

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Visit: V1_DAY1_VAX1_L

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Generated By: (b) (4)

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

Aug-08-2020 10:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/27/2020	Initial Entry
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I.y

Date	Location	User	Value	Reason
Aug-08-2020 10:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/ 25 MH N umber : Medic Stent placeme al Hist nt left anterior ory Te descending art rm: ery Start Jan/27/2020 Date: Ongoi NO ng: End Date: Jan/27/2020 0	Initial Entry

090177e196ae30b6\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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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.y Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25	Initial Entry

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

Date	Location	User	Value	Reason
Aug-08-2020 10:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Stent placement left anterior descending artery	Initial Entry

1.y Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2020	Initial Entry

1.y Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

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Aug-08-2020 10:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/27/2020	Initial Entry
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I.z

Date	Location	User	Value	Reason
Aug-08-2020 10:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 26 Medical History Term: Depressive on Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

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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-08-2020 10:27:56 (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-08-2020 10:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

1.z Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.z Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

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

Aug-08-2020 10:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.aa

Date	Location	User	Value	Reason
Aug-08-2020 10:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 27 Medical History Term: Insomni a Start Date: UNK/U NK/200 5 Ongoing: YES	Initial Entry

090177e196ae30b6\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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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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-08-2020 10:28:19 (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-08-2020 10:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Insomnia	Initial Entry

1.aa Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.aa Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.ab

Date	Location	User	Value	Reason
Aug-08-2020 10:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 28 H Num ber: Medica Transurethral I Histor resection of t y Term: he prostate Start D UNK/UNK/2 ate: 013 Ongoin NO g: End Date: UNK/UN K/2013	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.ab Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:29:32 (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-08-2020 10:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Transurethral resection of the prostate	Initial Entry

1.ab Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.ab Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:29:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2013	Initial Entry
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I.ac

Date	Location	User	Value	Reason
Aug-08-2020 10:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 29 H Numb er: Medical Right total k History nee replace Term: ment Start Da UNK/UNK/ te: 2018 Ongoing NO : End Date: UNK/UN K/2018	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject Initials: ---

Generated By: (b) (4)

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I.ac Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:30:16 (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-08-2020 10:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right total knee replacement	Initial Entry

I.ac Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

I.ac Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Generated By: (b) (4)

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

Aug-08-2020 10:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry
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1.ad

Date	Location	User	Value	Reason
Aug-08-2020 10:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 30 H Numb er: Medical Bilateral Ing History uinal Hernia Term: repair Start Da UNK/UNK/ te: 2005 Ongoing NO : End Date: UNK/UN K/2005	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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-08-2020 10:31:14 (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-08-2020 10:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilateral Inguinal Hernia repair	Initial Entry

1.ad Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.ad Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry
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1.ae

Date	Location	User	Value	Reason
Aug-14-2020 09:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 31 H Numb er: Medical Bilateral C History ataracts sur Term: gery Start Da UNK/UNK te: /1990 Ongoing NO : End Date: UNK/U NK/199 9	Initial Entry
Aug-08-2020 10:33:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 31 Number: Medical Bilateral History T Cataracts erm: surgery	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

			Start Date:	
			Ongoing:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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-08-2020 10:33:15 (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-08-2020 10:33:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilateral Cataracts surgery	Initial Entry

1.ae Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 09:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.ae Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-14-2020 09:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry
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1.af

Date	Location	User	Value	Reason
Aug-19-2020 16:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 32 H Numbr: Medical History Term: Tonsillectomy Start Date: UNK/UNK/1965 Ongoing: NO : End Date: UNK/ UNK/ 1965	Transcription Error
Aug-08-2020 10:33:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 32 Medical History Term: Tonsillectomy :	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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			Start Date:	
			Ongoing:	

Header Text: c4591001

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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-08-2020 10:33:44 (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-08-2020 10:33:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tonsillectomy	Initial Entry

1.af Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 16:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1965	Transcription Error

1.af Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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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Site No: 1129

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-19-2020 16:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1965	Transcription Error
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1.ag

Date	Location	User	Value	Reason
Aug-08-2020 10:34:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 33 Number: Medical History Term: Hemorrhoidectomy Start Date: UNK/UNK/1980 Ongoing: NO End Date: : UNK/UNK/1980	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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Lag Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:34:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33	Initial Entry

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

Date	Location	User	Value	Reason
Aug-08-2020 10:34:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemorrhoidectomy	Initial Entry

Lag Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:34:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

Lag Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Generated By: (b) (4)

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Aug-08-2020 10:34:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1980	Initial Entry
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1.ah

Date	Location	User	Value	Reason
Aug-08-2020 10:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 34 Number: Medical History Term: Hemorrhoidectomy Start Date: UNK/UNK/1995 Ongoing: NO End Date: : UNK/UNK/1995	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

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Subject No: 11291059

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-08-2020 10:34:58 (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-08-2020 10:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemorrhoidectomy	Initial Entry

1.ah Start Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:34:58 (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
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1995	Initial Entry
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1.ai

Date	Location	User	Value	Reason
Aug-14-2020 09:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 35 H Num ber: Medica right Shoul l Histor der reconst y Term ruction : Start D UNK/UN ate: K/1997 Ongoin NO g: End Date : UNK/U NK/199 7	Transcription Error
Aug-08-2020 10:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 35 Number:	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Generated By: (b) (4)

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

			Medical History Term: Should Start Date: Surgery Ongoing:	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject Initials: ---

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1.ai Line/MH Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:40:20 (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-14-2020 09:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right Shoulder reconstruction	Transcription Error
Aug-08-2020 10:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Shoulder Surgery	Initial Entry

1.ai Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 09:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1997	Transcription Error

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

I.ai Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 09:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1997	Transcription Error

I.aj

Date	Location	User	Value	Reason
Aug-13-2020 17:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 36 umber: Medical His Acid Ref tory Term: lux Start Date: UNK/U NK/197 0 Ongoing: YES	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

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-13-2020 17:28:18 (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-13-2020 17:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acid Reflux	Initial Entry

1.aj Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 17:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1970	Initial Entry

1.aj Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-13-2020 17:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.ak

Date	Location	User	Value	Reason
Aug-13-2020 17:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 37 umber: Medical Hi urination story Term problems : Start Date: UNK/UN K/2013 Ongoing: YES	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

1.ak Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 17:30:16 (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-13-2020 17:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: urination problems	Initial Entry

1.ak Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 17:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.ak Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-13-2020 17:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.a1

Date	Location	User	Value	Reason
Aug-14-2020 09:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 38 H Numb er: Medical right should History er reconstru Term: ction Start Da UNK/UNK/ te: 2005 Ongoing NO : End Date: UNK/UN K/2005	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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1.a1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 09:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 38	Initial Entry

1.a1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 09:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right shoulder reconst ruction	Initial Entry

1.a1 Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 09:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.a1 Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-14-2020 09:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry
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1.am

Date	Location	User	Value	Reason
Aug-19-2020 16:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 39 Medical History Term: nocturia Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

I.am Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 16:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 39	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 16:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nocturia	Initial Entry

I.am Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 16:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.am Ongoing:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-19-2020 16:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.an

Date	Location	User	Value	Reason
Aug-19-2020 16:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 40 H Number: Medical History Term: tonsillitis Start Date: UNK/UNK/1965 Ongoing: NO : End Date:	Transcription Error
Aug-19-2020 16:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 40 :	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Medicinal History Term: Transurethral resection of the prostate</p> <p>Start Date: UNK/UNK/2013</p> <p>Ongoing: NO</p> <p>End Date: UNK/UNK/2013</p>	
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090177e196ae30b6\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: 11291059

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-19-2020 16:22:37 (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-19-2020 16:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tonsillitis	Transcription Error
Aug-19-2020 16:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Transurethral resection of the prostate	Initial Entry

1.an Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 16:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1965	Transcription Error

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-19-2020 16:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry
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1.an Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 16:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1965	Transcription Error
Aug-19-2020 16:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2013	Initial Entry

090177e196ae30b6\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: 11291059

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/7/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 160.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 67.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Ide 1	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)			ntifier:: Temperatu 97.6 re: Temperatu F re Unit: Temperatu ORAL re Location CAVIT :: Y
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (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-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-08-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30b6\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: 11291059

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-08-2020 10:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/7/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-08-2020 10:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 224051	Initial Entry

090177e196ae30b6\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: 11291059

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: ---

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1. Data Origin

Date	Location	User	Value	Reason
Aug-07-2020 17:57:01 (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-07-2020 17:57:01 (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-07-2020 17:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/7/2020	Transcription Error
Aug-07-2020	ACV0PFEINFP6000	auto query	Query 2: Closed	Close Auto

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

17:57:15 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Query
Aug-07-2020 17:57:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-07-2020 17:57:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Aug-07-2020 17:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Aug-07-2020 17:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

				protocol, please provide reason' is missing. Please review and update as appropriate.
Aug-07-2020 17:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-07-2020 17:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP5PW D: P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 17:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PWP	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Aug-07-2020 17:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP5PW D: R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 17:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PWR	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-07-2020 17:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP5PW D: S	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 17:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PWS	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-07-2020 17:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BLD1F D: D	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 17:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD1FD	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 17:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BLD1F : F	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 17:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD1FF	Initial Entry

090177e196ae30b6\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: 11291059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Aug-07-2020 17:59:16 (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-07-2020 17:59:16 (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-07-2020 17:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/7/2020	Initial Entry

5.a

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-07-2020 17:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5PJ : L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 17:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PJL	Initial Entry

090177e196ae30b6\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: 11291059

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-08-2020 10:42:07 (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-08-2020 10:42:07 (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-08-2020 10:42:07 (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
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-08-2020 10:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/7/2020 13:45	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-08-2020 10:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-08-2020 10:42:07 (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-08-2020 10:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-08-2020 10:42:07 (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-08-2020 10:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b6\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: 11291059

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-08-2020 10:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGEN ICITY E-DIARY CO LLECTED FOR THI S SUBJECT	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291059

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 14:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

090177e196ae30b6\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: 11291059

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-28-2020 14:39:11 (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-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptom O s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (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-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae30b6\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: 11291059

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.c Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (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-28-2020 14:39:11 (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-28-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

14:39:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Symptom::	C HI L LS
		Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	

2.d Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (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-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary was completed ?:	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (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-28-2020 14:39:11 (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-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA	Initial Entry

090177e196ae30b6\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: 11291059

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.f Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (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-28-2020 14:39:11 (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-28-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

<p>14:39:11 (UTC-05:00) Eastern Time (US & Canada)</p>		<p>(b) (4), (b) (6)</p>	<p>Symptom:: NEW OR W ORSE NED MUS CLE P AIN</p> <p>Were fever o NO r systemic sy mptoms pre sent on the l ast day the S ubject Diary was complet ed?:</p>	
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOIN T 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-28-2020 14:39:11 (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-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED JOIN T PAIN	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or NO r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?:	
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2.h Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSEN ED JOINT 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-28-2020 14:39:11 (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
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (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-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE D NE SS Were injection site reactions present on the last day the Subject Diary was completed?: N O	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (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-28-2020 14:39:11 (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-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site R SW eaaction:: EL LI NG	Initial Entry

090177e196ae30b6\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: 11291059

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-28-2020 14:39:11 (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-28-2020 14:39:11 (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-28-2020 14:39:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAI	Initial Entry

090177e196ae30b6\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: 11291059

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)	Reaction:: N AT INJE CTI ON SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b6\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: 11291059

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-28-2020 14:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-28-2020 14:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.3 Temperature Unit: Temperature Location: ORAL CAVIT Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:28 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 14:39:28 (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-28-2020 14:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30b6\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: 11291059

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-28-2020 18:41:33 (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-28-2020 18:41:33 (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-28-2020 18:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 18:41:33	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 18:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 18:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BMB5F : 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 18:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMB5F3	Initial Entry

090177e196ae30b6\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: 11291059

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-28-2020 14:40:02 (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-28-2020 14:40:02 (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-28-2020 14:40:02 (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
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090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020 11:58	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 14:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-28-2020 14:40:02 (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-28-2020 14:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30b6\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: 11291059

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-28-2020 14:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b6\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: 11291059 **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-25-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptom O s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196ae30b6\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: 11291059 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:25

2.b Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae30b6\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: 11291059 **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.c Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (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-25-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

15:01:15 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Symptom:: C HI L LS Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:
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2.d Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary was completed? :	Initial Entry

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

2.e Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (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-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA	Initial Entry

090177e196ae30b6\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: 11291059 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.f Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-25-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

15:01:15
(UTC-05:00)
Eastern Time (US
& Canada)

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

Symptom:: NEW
OR W
ORSE
NED
MUS
CLE P
AIN

Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO

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: 11291059 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:25

2.g Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE ED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED JOIN T PAI N	Initial Entry

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

			Were fever or NO r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?:	
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2.h Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSEN ED JOINT 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-25-2020 15:01:15 (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
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090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE D NE SS Were injection site reactions present on the last day the Subject Diary was completed?: N O	Initial Entry

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (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-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LI NG	Initial Entry

090177e196ae30b6\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: 11291059 **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?:	NO
--	--	--	---	----

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (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-25-2020 15:01:15 (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-25-2020 15:01:15	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAI	Initial Entry

090177e196ae30b6\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: 11291059 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)	Reaction:: N AT INJE CTI ON SITE Were injection site reactions present on the last day the Subject Diary was completed?:	NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTIO N SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 15:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b6\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: 11291059 **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-25-2020 13:16:14 (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-25-2020 13:16:14 (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-25-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 13:16:14	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b6\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: 11291059 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 13:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BLD19 : 9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD199	Initial Entry

5.b

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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Sep-25-2020 13:16:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BLD19 : 8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 13:16:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD198	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-25-2020 13:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPC00 : H	Initial Entry

090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 13:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC00H	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-25-2020 13:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPC00J	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 13:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC00J	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Sep-25-2020 13:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPC00 : K	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 13:17:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC00K	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291059

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
Feb-25-2021 08:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query.
Feb-24-2021 14:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-22-2021 08:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing SAMP TRK form or else clarify. Thank you.
Feb-19-2021 11:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/19/2021	Initial Entry

090177e196ae30b6\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: 11291059

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-24-2021 13:57:47 (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-24-2021 13:57:47 (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-24-2021 13:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 13:57:47	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-24-2021 13:57:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-24-2021 13:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BSFMY : 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFMY8	Initial Entry

5.b

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-24-2021 13:58:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BSFMY : 9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:58:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFMY9	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-24-2021 13:58:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BTZPN : 3	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:58:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPN3	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-24-2021 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BTZPN : 4	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPN4	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Feb-24-2021 13:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BTZPN : 5	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPN5	Initial Entry

090177e196ae30b6\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: 11291059 **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
Sep-28-2020 10:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-28-2020 10:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-28-2020 10:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Feb-19-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 17:14:47 (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
Nov-05-2020 17:14:47 (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
Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left supraclavicular a denopathy	Initial Entry

4. Start Date Time:

090177e196ae30b6\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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 08:27:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-18-2020 11:54:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	per subject AE has improved however not resolved
Dec-14-2020 06:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 2: Opened	Clin: Please confirm if this AE is still ongoing
Nov-09-2020 14:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query

090177e196ae30b6\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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Nov-09-2020 13:26:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	recovering/resolving accurate per subject contact 5Nov2020
Nov-07-2020 09:59:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Opened	Clin: Left supraclavicular adenopathy is currently marked as ongoing (start date >28 days ago), however this appears to be a temporary condition. Please provide an end date or clarification.
Nov-05-2020 17:14:47 (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
Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae30b6\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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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
Nov-05-2020 17:14:47 (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
Nov-05-2020 17:14:47 (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
Nov-05-2020 17:14:47 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e196ae30b6\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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 17:14:47 (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
Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

090177e196ae30b6\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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RES OLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-05-2020 17:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b6\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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Feb-19-2021 12:09:05 (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-19-2021 12:09:05 (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
Feb-19-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: worsening hypertensi on	Initial Entry

4. Start Date Time:

090177e196ae30b6\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

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-19-2021 12:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-19-2021 12:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-19-2021 12:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2021 08:00	Transcription Error
Feb-19-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For worsening hypertension: Start date 01/Jan/2020 is before V1D1VX1L visit date 07/Aug/2020. Please review and update as appropriate.
Feb-19-2021 12:09:05 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start date is before Consent Date 07/Aug

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				/2020.
Feb-19-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-19-2021 12:09:05 (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-19-2021 12:09:05 (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;

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Subject Initials: ---

Generated By: (b) (4)

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Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-19-2021 12:09:05 (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-19-2021 12:09:05 (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-19-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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			<i>If Other, specify:</i>	
			unknown etiology	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-19-2021 12:09:05 (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-19-2021 12:09:05 (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
Feb-19-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-19-2021 12:09:05 (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-19-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059 **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
Dec-18-2020 13:41:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1129 **Site Name:** (1129) Jacksonville Center for Clinical
Research

Subject No: 11291059 **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
Dec-18-2020 13:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing t o return for Vaccinati on 3 Participant is: eligible and NOT confirmed to have received only plac ebo at Vaccination 1/2	Initial Entry

090177e196ae30b6\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: 11291059

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
Dec-18-2020 13:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-18-2020 13:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae30b6\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: 11291059

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-28-2020 10:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-08-2020 10:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-07-2020 17:50:08 (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
Sep-28-2020 10:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Initial Entry
Aug-08-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae30b6\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: 11291059

Subject Initials: ---

Generated By: (b) (4)

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

10:41:37 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Aug/7/2020	
Aug-07-2020 17:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/7/2020	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291059

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - 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. Casebook Signature

Date	Location	User	Value	Reason
Sep-11-2020 11:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30b6\Final\Final On: 01-Apr-2021 04:14 (GMT)