

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: 11291032

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	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae30b8\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: 11291032

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/3/2020
----	--------------	---

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11291032]
2.	Birth Date:	(b) (6)/1948
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:	

090177e196ae30b8\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: 11291032

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/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

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

[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

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

1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

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

2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

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

2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

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

2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

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

2.1	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

090177e196ae30b8\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: 11291032

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

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/1960
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[kidney stones]
	Start Date:	Feb/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[bilateral cataracts]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: Dec/UNK/2019

090177e196ae30b8\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: 11291032

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:	[asthma]
	Start Date:	UNK/UNK/1960
	Ongoing:	NO End Date: UNK/UNK/1982
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[osteoarthritis]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[intermittent gout]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

090177e196ae30b8\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: 11291032

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:	[fracture right tibia]
	Start Date:	UNK/UNK/1963
	Ongoing:	NO End Date: UNK/UNK/1963
1.h	Line/MH Number:	[8]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[right fibula fracture]
	Start Date:	UNK/UNK/1963
	Ongoing:	NO End Date: UNK/UNK/1963
1.i	Line/MH Number:	[9]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Neck pain]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2010

090177e196ae30b8\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: 11291032

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:	[type 2 diabetes]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[high cholesterol]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[overweight]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[high blood pressure]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

090177e196ae30b8\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: 11291032

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.n	Line/MH Number:	[14]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[abnormal electrocardiogram]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Chronic major depression]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[bilateral cataract surgery]
	Start Date:	Dec/UNK/2019
	Ongoing:	NO End Date: Dec/UNK/2019

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.q	Line/MH Number:	[17]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[right shoulder replacement]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.r	Line/MH Number:	[18]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[bilateral shoulder surgery]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.s	Line/MH Number:	[19]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[surgical fixture c-3-4-5]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

090177e196ae30b8\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: 11291032

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.t	Line/MH Number:	[20]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[bilateral knee replacement]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002
1.u	Line/MH Number:	[21]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[bilateral arthroscopic knee surgery x2]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999
1.v	Line/MH Number:	[22]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[smoker]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/3/2020
2.	Weight:	[226.6]
3.	Unit:	LB
4.	Height:	[70.0]
5.	Unit:	in
6.	Body Mass Index:	[32.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30b8\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: 11291032

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/3/2020
2.	Randomization Number:	[221441]
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:** 11291032**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/3/2020
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	[BP5PZY]
5.b	Sample ID	[BP5PZZ]
5.c	Sample ID	[BP5R00]
5.d	Sample ID	[BLD17W]
5.e	Sample ID	[BLD17V]

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: 11291032

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/3/2020
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	[BP5R26]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291032

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/3/2020 10:50
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

090177e196ae30b8\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: 11291032

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: 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: 11291032

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	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1129

Subject No: 11291032

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

090177e196ae30b8\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: 11291032

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

090177e196ae30b8\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: 11291032

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

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/24/2020
----	-------	-------------

Vital Signs Details

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

090177e196ae30b8\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: 11291032

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/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BMB572]
-----	-----------	----------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/24/2020 12:21
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

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 11291032 **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

090177e196ae30b8\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: 11291032 **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

090177e196ae30b8\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: 11291032 **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

090177e196ae30b8\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:** 11291032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPC03L]
5.b	Sample ID	[BPC03K]
5.c	Sample ID	[BPC03J]
5.d	Sample ID	[BLD0XT]
5.e	Sample ID	[BLD0XV]

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1129

Subject No: 11291032

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

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

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

090177e196ae30b8\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: 11291032

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

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: 11291032

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?	
----	--	--

090177e196ae30b8\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: 11291032

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001
Visit: POT_COVID_CONVA - New
 Unscheduled Visit
Form Version: 22-Apr-2020 21:03
Form Status: Not Started
Site No: 1129
Site Name: (1129) Jacksonville Center for Clinical
 Research
Subject No: 11291032
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: 11291032 **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: 11291032 **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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

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

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291032

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: 11291032

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

090177e196ae30b8\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: 11291032 **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	[]
----	-----------	-----

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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	fatigue	Jan/25/2021 UNK:UNK	NO End Date Time: Jan/25/2021 U NK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	vomiting	Jan/25/2021 UNK:UNK	NO End Date Time: Jan/25/2021 U NK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	generalized body ache	Jan/25/2021 UNK:UNK	NO End Date Time: Jan/31/2021 U NK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	chills	Jan/25/2021 UNK:UNK	NO End Date Time: Jan/25/2021 U NK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	mild fever	Jan/25/2021 UNK:UNK	NO End Date Time:	Repeating Pages

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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
					Jan/25/2021 UNK:UNK	
6.	ADVERSE EVENT	6	worsened degenerative joint disease left shoulder	Feb/16/2021 UNK:UNK	NO End Date Time: Feb/17/2021 UNK:UNK	Repeating Pages

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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)	[fatigue]
4.	Start Date Time:	Jan/25/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/25/2021 UNK:UNK
6.	Toxicity Grade:	3

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

[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)	[vomiting]
4.	Start Date Time:	Jan/25/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/25/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[generalized body ache]
4.	Start Date Time:	Jan/25/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/31/2021 UNK:UNK
6.	Toxicity Grade:	3

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chills]
4.	Start Date Time:	Jan/25/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/25/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[mild fever]
4.	Start Date Time:	Jan/25/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/25/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsened degenerative joint disease left shoulder]
4.	Start Date Time:	Feb/16/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/17/2021 UNK:UNK
6.	Toxicity Grade:	3

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
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: [degenerative joint disease]

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021195295]

090177e196ae30b8\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: 11291032

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

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1129

Subject No: 11291032

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	[]

090177e196ae30b8\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: 11291032

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae30b8\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: 11291032

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

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae30b8\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: 11291032

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

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291032

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?	

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

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: 11291032

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:	

090177e196ae30b8\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: 11291032

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?	

090177e196ae30b8\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: 11291032

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: 11291032

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: 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: 11291032 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

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: 11291032 **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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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	Jan/4/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/4/2021
----	--------------	---

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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
----	--	----------------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291032**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: Jan/4/2021
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	[BLB4Z0]
5.b	Sample ID	[BLB4Z1]
5.c	Sample ID	[BRL3SJ]
5.d	Sample ID	[BRL3SK]
5.e	Sample ID	[BRL3SL]

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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: Jan/4/2021
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	[BRL3PW]
-----	-----------	----------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/4/2021 15:55
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/4/2021
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: 11291032

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: 11291032

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:	[]

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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	Jan/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRMX0S]
-----	-----------	----------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/25/2021 13:16
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291032

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/22/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: CONTACT OUTCOME

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](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/22/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291032

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291032

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

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 :	Feb/22/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-12-2021 15:39:22 (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: 11291032

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-04-2021 14:08:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Michael Koren	Approved	Jan-27-2021 21:37:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

Affidavit:

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

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

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

(b) (6)	N/A	Jan-26-2021 09:49:09 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

Michael Koren	Approved	Jan-25-2021 18:05:56 (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	Jan-22-2021 15:02:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	---

Affidavit:

N/A

Michael Koren	Approved	Jan-21-2021 17:51:38 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

090177e196ae30b8\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: 11291032

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	Jan-12-2021 15:36:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	---

Affidavit:

N/A

Michael Koren	Approved	Oct-14-2020 09:48:04 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
------------------	----------	--	------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

(b) (6)	N/A	Sep-21-2020 12:05:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

Michael Koren	Approved	Sep-11-2020 12:06:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	--	------	--------

090177e196ae30b8\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: 11291032

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.

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: 11291032

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-03-2020 12:15:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-03-2020 12:15:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHOR TS	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-03-2020 12:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/3/2020	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11291032	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1948	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-03-2020 12:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry
---	-----------------	---------------------	---	---------------

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

Date	Location	User	Value	Reason
Aug-03-2020 12:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 1 usion Number: Crit Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) Crit YES or no?:	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

			Crit IN01A00 erion I D: (For Pfizer use only) :	
--	--	--	---	--

1.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (depende	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

			nt upon study stage)	
--	--	--	----------------------	--

1.a Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 2 usio n N um ber:	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Crit Participants erio who are willi n D ng and able t escr o comply wit ipti h all schedule on: d visits, vacci nation plan, l aboratory test s, lifestyle co nsiderations, and other stu dy procedure s</p> <p>Crit YES erio n m et?:</p> <p>Crit IN02A00 erio n ID : (F or P fize r us e on ly):</p>	
--	--	--	---	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.b Inclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

I.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 3 usio n N um ber: Crit Healthy parti erio cipants who a n D re determined eser by medical hi ipti story, physica on: l examination , and clinical judgment of t he investigato r to be eligibl e for inclusio n in the study	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crit YES erio n m et?: Crit IN03A00 erio n I D: (For Pfiz er u se o nly) :	
--	--	--	--	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

I.c Inclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 4 usio n N um ber: Crit Capable of gi erio ving personal n D signed inform escr ed consent, w ipti hich includes on: compliance w ith the require ments and res trictions liste d in the ICD and in this pr otocol	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crit YES erion met?: Crit IN04A00 erion ID : (F or P fizer use only):	
--	--	--	---	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.d Inclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving p ersonal signed infor med consent, which includes complianc e with the requirem ents and restrictions listed in the ICD an d in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 1 lusi on Nu mbe r: Crit Other medica erio l or psychiatri n D c condition in escr cl. recent (wit ipti hin past year) on: or active suici dal ideation/b ehavior/lab a bnormality th at may increa se the risk of study particip ation	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical
Research**Subject No:** 11291032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

			Crit NO erio n m et?: Crit EX01A00 erio n I D: (For Pfiz er u se o nly) :	
--	--	--	---	--

2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Other medical or ps ychiatric condition i ncl. recent (within p ast year) or active s	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

			uicidal ideation/behavior/lab abnormality that may increase the risk of study participation	
--	--	--	---	--

2.a Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 2 usio n Nu	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

			<p>mbe</p> <p>r:</p> <p>Crite Known infec rion tion with hu Desc man immun ripti odeficiency on: virus (HIV), hepatitis C v irus (HCV), or hepatitis B virus (HB V)</p> <p>Crite NO rion met? :</p> <p>Crite EX02A00 rion ID: (For Pfize r use only) :</p>	
--	--	--	--	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry
---	-----------------	---------------------	-------------------------------	---------------

2.c

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 3 usio n N umb er: Crit History of se erio vere adverse n D reaction asso escr ciated with a iptio vaccine and/o n: r severe aller gic reaction (eg, anaphylaxis) to any component of the study intervention(s) Crit NO erio n m et?:	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crit EX03A00 erio n ID : (F or P fizer use only):	
--	--	--	---	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe ad verse reaction assoc iated with a vaccine and/or severe allergi c reaction (eg, anap hylaxis) to any com ponent of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Receipt of medication intended to prevent COVID-19 Criterion met?: NO Criterion ID: (For Pfizer use only): EX04A00	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry
---	-----------------	---------------------	-------------------------------	---------------

2.e

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 8 usio n N umb er: Crit Immunocom erio promised indi n De viduals with scri known or sus ptio pected immu n: nodeficiency, as determine d by history a nd/or laborat ory/physical examination Crit NO erio n m et?:	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crit EX08A00 erio n ID : (F or P fizer use only):	
--	--	--	---	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromis ed individuals with known or suspected immunodeficiency, as determined by hi story and/or laborat ory/physical examin ation	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 10 usio n N umb er: Crit Bleeding diat erio hesis or condi n De tion associate scri d with prolon ptio ged bleeding n: that would, in the opinion o f the investig ator, contrain dicate intram uscular inject ion	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crit NO erio n m et?: Crit EX10A00 erio n ID : (F or P fizer use only):	
--	--	--	---	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Criterion met?: Criterion ID: (For Pfizer use only): EX11A0 0	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pre gnant or breastfeedi ng	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry
---	-----------------	---------------------	-------------------------------	---------------

2.h

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: (For Pfizer use only): EX12A00	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry
---	-----------------	---------------------	-------------------------------	---------------

2.i

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 13 usion Num ber: Crite Subjects wh riou o receive im Desc munosuppre ripti ssive therap on: y, such as cy totoxic agen ts or systemi c corticoster oids Crite NO riou met? :	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crite EX13A01 rion ID: (For Pfize r use only) :	
--	--	--	---	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry
---	-----------------	---------------------	-------------------------------	---------------

2.j

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 15 usio n N umb er: Crit Receipt of bl erio ood/plasma p n De roducts or im scri munoglobuli ptio n, from 60 da n: ys before stu dy interventi on administra tion or planne d receipt thro ughout the st udy Crit NO erio n m et?:	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crit EX14A01 erio n ID : (F or P fizer use only):	
--	--	--	---	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

2.k

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 16 usio n Nu mbe r: Crit Participation erio in other stud n De ies involving scrip study interve tion: ntion within 28 days prio r to study ent ry and/or dur ing study par ticipation Crit NO erio n me t?:	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crit EX15A01 erio n ID : (Fo r Pfi zer use only):	
--	--	--	---	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and /or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.1

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 17 usion Num ber: Crite Previous pa rion rticipation i Desc n other stud ription ies involvin n: g study inte rvention co ntaining lipi d nanoparti cles Crite NO rion met? :	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

			Crite EX16A01 rion ID: (For Pfize r use only) :	
--	--	--	---	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participati on in other studies i nvolving study inte rvention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry
---	-----------------	---------------------	-------------------------------	---------------

2.m

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 22 lusi on Nu mb er: Crit Investigator s erio ite staff or Pfi n D zer employee escr s directly inv ipti olved in the c on: onduct of the study, site sta ff otherwise s upervised by the investigat or, and their r espective fam ily members	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Crit NO erion met?: Crit EX21A01 erion n I D: (For Pfizer use only) :</p>	
--	--	--	--	--

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-03-2020 12:16:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-03-2020 12:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-03-2020 12:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-03-2020 12:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30b8\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:** 11291032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-03-2020 12:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 1 umber: Medical His seasonal tory Term: allergies Start Date: UNK/U NK/196 0 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:18:25 (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-03-2020 12:18:25 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: seasonal allergies	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: 11291032

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-03-2020 12:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1960	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-03-2020 12:18:25 (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-03-2020 12:20:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical H kidney sto istory Ter nes m:	Initial Entry

090177e196ae30b8\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: 11291032

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

			Start Date Feb/UNK/ : 2019 Ongoing: NO End Date : UNK/U NK/201 9	
--	--	--	--	--

090177e196ae30b8\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: 11291032

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-03-2020 12:20:01 (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-03-2020 12:20:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kidney stones	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:20:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/UNK/2019	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:20:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry
--	-----------------	---------------------	---	---------------

I.c

Date	Location	User	Value	Reason
Aug-03-2020 12:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 3 H Num ber: Medical bilateral History cataracts Term: Start D UNK/U ate: NK/201 7 Ongoin NO g: End D ate: Dec/ UNK /2019	Transcription Error
Aug-03-2020 12:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 3 H Num ber:	Transcription Error

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

			Medical History Term: Start Date: UNK/UNK/2017 Ongoing: NO End Date: Dec/UNK/2019	
Aug-03-2020 12:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/Marker: 3 Medical History Term: Start Date: Dec/UNK/2019 Ongoing: NO End Date: Dec/UNK/2019	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:20:49 (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-03-2020 12:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral cataracts	Transcription Error
Aug-03-2020 12:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cataracts	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Transcription Error

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/UNK/2019	Initial Entry
---	-----------------	---------------------	------------------------------------	---------------

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-03-2020 12:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/UNK/2019	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-03-2020 12:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4 Number: Medical History Term: asthma Start Date UNK/UNK/1960	Initial Entry

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

			Ongoing: NO	
			End Date	
			:	
			UNK/U	
			NK/198	
			2	

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: 11291032

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-03-2020 12:21:19 (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-03-2020 12:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: asthma	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:21:19 (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
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1982	Initial Entry
---	-----------------	---------------------	---	---------------

I.e

Date	Location	User	Value	Reason
Aug-03-2020 12:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 5 umber: Medical His osteoarth tory Term: ritis Start Date: UNK/U NK/201 0 Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:21:43 (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-03-2020 12:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: osteoarthritis	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
--	-----------------	---------------------	---------------------------	---------------

If

Date	Location	User	Value	Reason
Aug-03-2020 12:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: intermittent gout Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:22:14 (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-03-2020 12:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: intermittent gout	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:22:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
--	-----------------	---------------------	---------------------------	---------------

I.g

Date	Location	User	Value	Reason
Aug-03-2020 12:23:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 7 Number: Medical History Term: fracture right tibia Start Date: UNK/UNK/1963 Ongoing: NO End Date: UNK/UNK/1963	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:23:13 (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-03-2020 12:23:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fracture right tibia	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:23:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1963	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:23:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1963	Initial Entry
--	-----------------	---------------------	---	---------------

1.h

Date	Location	User	Value	Reason
Aug-03-2020 12:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 8 Number: Medical History Term: right fibula fracture Start Date: UNK/UNK/1963 Ongoing: NO End Date: UNK/UNK/1963	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:24:00 (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-03-2020 12:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right fibula fracture	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1963	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1963	Initial Entry
--	-----------------	---------------------	---	---------------

1.i

Date	Location	User	Value	Reason
Aug-03-2020 13:31:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 9 H Number: Medical History Term: Neck pain Start Date: UNK/UNK/2007 Ongoing: NO : End Date: UNK/ UNK/ 2010	Initial Entry
Aug-03-2020 12:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 9 H Number:	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

			Medical History Term: Neck pain Start Date: Ongoing NO : End Date: UNK/ UNK/ 2010	
Aug-03-2020 12:25:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Neck pain Start Date: Ongoing:	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:25:02 (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-03-2020 12:25:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neck pain	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 13:31:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2007	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-03-2020 12:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-03-2020 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 10 Medical His tory Term: type 2 di abetes Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:25:27 (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-03-2020 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: type 2 diabetes	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
--	-----------------	---------------------	---------------------------	---------------

1.k

Date	Location	User	Value	Reason
Aug-03-2020 12:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 11 Medical History Term: high cholesterol Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:26:01 (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-03-2020 12:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: high cholesterol	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
--	-----------------	---------------------	---------------------------	---------------

1.1

Date	Location	User	Value	Reason
Aug-03-2020 12:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 12 Medical History Term: overweight Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:26:39 (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-03-2020 12:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: overweight	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
--	-----------------	---------------------	---------------------------	---------------

1.m

Date	Location	User	Value	Reason
Aug-03-2020 12:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 13 umber: Medical Hi high bloo story Term d pressur : e Start Date: UNK/UN K/2016 Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:28:02 (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-03-2020 12:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: high blood pressure	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:28:02 (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-03-2020 12:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 14 Number: Medical History T abnormal e lectrocardiogram Start Date: UNK/UNK /2010 Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:28:40 (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
Sep-09-2020 23:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Closed	Response satisfies query
Sep-09-2020 16:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	records received, records did not address abnormal EKG
Aug-14-2020 15:03:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Reissued: Opened	Page needs to be unfrozen for site edits.
Aug-12-2020 10:38:20 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	correct as entered. Medical records requested

090177e196ae30b8\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:** 11291032**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25

Eastern Time (US & Canada)				to clarify
Aug-11-2020 17:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Opened	Per MM review, please provide specific diagnosis or abnormal electrocardiogram finding.
Aug-03-2020 12:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: abnormal electrocardiogram	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Aug-03-2020 12:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.o

Date	Location	User	Value	Reason
Aug-03-2020 12:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 15 Number: Medical History Term: Chronic major depression Start Date: UNK/UNK/1970 Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:30:16 (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-03-2020 12:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic major depression	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1970	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
--	-----------------	---------------------	---------------------------	---------------

1.p

Date	Location	User	Value	Reason
Aug-03-2020 12:33:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 16 Number: Medical History bilateral cat T aract surger erm: y Start Date: Dec/UNK/2 019 Ongoing: NO End Date: Dec/UNK/2019	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:33:48 (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-03-2020 12:33:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral cataract surgery	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:33:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/UNK/2019	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:33:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/UNK/2019	Initial Entry
--	-----------------	---------------------	---	---------------

1.q

Date	Location	User	Value	Reason
Aug-03-2020 12:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 17 Number: Medical History Term: right should er replacem ent Start Date: UNK/UNK/ 2017 Ongoing: NO End Date: UNK/U NK/2017	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:35:17 (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-03-2020 12:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right shoulder replacement	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry
--	-----------------	---------------------	---	---------------

l.r

Date	Location	User	Value	Reason
Aug-03-2020 12:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 18 Number: Medical History bilateral sho T ulder surger erm: y Start Date: UNK/UNK/ 2015 Ongoing: NO End Date: UNK/U NK/201 5	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Aug-03-2020 12:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral shoulder surgery	Initial Entry

1.r Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I.r Ongoing:

Date	Location	User	Value	Reason
Aug-03-2020 12:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

I.s

Date	Location	User	Value	Reason
Aug-03-2020 12:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 19 Number: Medical History Term: surgical fix ture c-3-4-5 Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:36:42 (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-03-2020 12:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: surgical fixture c-3-4-5	Initial Entry

1.s Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.s Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry
--	-----------------	---------------------	---	---------------

1.t

Date	Location	User	Value	Reason
Aug-03-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 20 Number: Medical History Term: bilateral knee replacement Start Date: UNK/UNK/2002 Ongoing: NO End Date: UNK/UNK/2002	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:37:09 (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-03-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral knee replacement	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2002	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2002	Initial Entry
--	-----------------	---------------------	---	---------------

I.u

Date	Location	User	Value	Reason
Aug-03-2020 12:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 21 H Num ber: Medica bilateral arthr I Histor oscopic knee y Term: surgery x2 Start D UNK/UNK/1 ate: 999 Ongoin NO g: End Date: UNK/UN K/1999	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:37:59 (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-03-2020 12:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral arthroscopic knee surgery x2	Initial Entry

1.u Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1999	Initial Entry

1.u Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry
--	-----------------	---------------------	---	---------------

I.v

Date	Location	User	Value	Reason
Aug-03-2020 13:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 22 Number: Medical smoker History T erm: Start Dat UNK/ e: UNK/2 010 Ongoing: YES	Initial Entry
Aug-03-2020 12:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 22 mber: Medical Hist smo ory Term: ker Start Date: Ongoing: YES	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

1.v Line/MH Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

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

Date	Location	User	Value	Reason
Aug-03-2020 12:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: smoker	Initial Entry

1.v Start Date:

Date	Location	User	Value	Reason
Aug-03-2020 13:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.v Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
---	-----------------	---------------------	---------------------------	---------------

090177e196ae30b8\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: 11291032

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-03-2020 12:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-03-2020 12:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 226.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-03-2020 12:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-03-2020 12:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 70.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-03-2020 12:40:05 (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-03-2020 12:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-03-2020 12:40:05 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)			entifier:: Temperat 98.8 ure: Temperat F ure Unit: Temperat ORAL ure Locati CAVIT on:: Y
----------------------------	--	--	---

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-03-2020 12:40:05 (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-03-2020 12:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry
---	-----------------	---------------------	-------------------------	---------------

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-03-2020 12:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30b8\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: 11291032

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-03-2020 12:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-03-2020 12:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 221441	Initial Entry

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-03-2020 12:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-03-2020 12:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-03-2020 14:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-03-2020 12:40:30	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b8\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:** 11291032**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-03-2020 12:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Aug/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-03-2020 14:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP5PZ D: Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PZY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Aug-03-2020 14:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP5PZ D: Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PZZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-03-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP5R0 D: 0	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5R00	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-03-2020 14:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BLD17 D: W	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD17W	Initial Entry

5.e

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BLD17 D: V	Initial Entry
--	-----------------	---------------------	--	---------------

5.e Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD17V	Initial Entry

090177e196ae30b8\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: 11291032

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-03-2020 12:40:39 (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-03-2020 12:40:39 (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-03-2020 14:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-03-2020 12:40:39	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b8\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: 11291032

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-03-2020 12:40:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Aug/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-03-2020 14:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP5R2 D: 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5R26	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:41:01 (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-03-2020 12:41:01 (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-03-2020 12:41:01 (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
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-03-2020 12:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020 10:50	Initial Entry
--	-----------------	---------------------	--	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-03-2020 12:41:01 (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-03-2020 12:41:01 (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-03-2020 12:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:41:01 (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-03-2020 12:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b8\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: 11291032

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-03-2020 12:41:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGE NICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae30b8\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: 11291032

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-24-2020 15:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020	Initial Entry

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: 11291032

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
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (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 Sub ject Diary was c ompleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
--	-----------------	---------------------	-----------------------------	---------------

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

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F A T I G U E Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?:	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (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-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae30b8\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: 11291032

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? :	
--	--	--	---	--

2.c Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (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-24-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

15:46:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Symptom::	C HI L L S N O
		Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.d Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.e

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (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-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA	Initial Entry

090177e196ae30b8\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: 11291032

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? :	
--	--	--	---	--

2.f Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (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-24-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

15:46:11
(UTC-05:00)
Eastern Time (US
& Canada)

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

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

**Were fever o NO
r systemic s
ymptoms pr
esent on the
last day the
Subject Diar
y was compl
eted?:**

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (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

090177e196ae30b8\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: 11291032

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?:	
--	--	--	--	--

2.h Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (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
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
---	-----------------	-------------------------	--------------------------------------	---------------

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: D NE SS Were injection site reactions present on the last day the Subject Diary was completed?: N O	Initial Entry

090177e196ae30b8\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: 11291032

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-24-2020 15:46:11 (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-24-2020 15:46:11 (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-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site SW Reaction:: EL LI NG	Initial Entry

090177e196ae30b8\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: 11291032

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
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (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-24-2020 15:46:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAI	Initial Entry

090177e196ae30b8\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: 11291032

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
--	--	------------------	--

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-24-2020 15:46:11 (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-24-2020 15:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\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: 11291032

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-24-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-24-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 98.2 Temperature Unit: Temperature Location: ORAL CAVIT Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 15:47:19 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae30b8\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: 11291032

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-24-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-24-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-26-2020 17:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-26-2020 17:39:53 (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-26-2020 17:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-26-2020 17:39:53	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b8\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: 11291032

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-26-2020 17:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 17:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BMB57 : 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 17:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMB572	Initial Entry

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-24-2020 15:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-24-2020 15:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-24-2020 15:48:19 (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
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Aug-24-2020 15:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/24/2020 12:21	Initial Entry
--	-----------------	---------------------	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-24-2020 15:48:19 (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-24-2020 15:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-24-2020 15:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30b8\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: 11291032

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-24-2020 15:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 15:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 12:05:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae30b8\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: 11291032 **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-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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 Sub ject Diary was c ompleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032 Subject Initials: ---

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

Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
---	-----------------	---------------------	-----------------------------	---------------

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

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?:	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

2.b Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae30b8\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: 11291032 **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? :	
--	--	--	---	--

2.c Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-21-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

12:06:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Symptom:: C HI L L S 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
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

2.e

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA	Initial Entry

090177e196ae30b8\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: 11291032 **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? :	
--	--	--	---	--

2.f Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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-21-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

12:06:53
(UTC-05:00)
Eastern Time (US
& Canada)

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

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

**Were fever o NO
r systemic sy
mptoms pre
sent on the l
ast day the S
ubject Diary
was complet
ed?:**

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED 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-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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

090177e196ae30b8\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: 11291032 **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?:	
--	--	--	--	--

2.h Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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-21-2020 12:06:53 (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
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
---	-----------------	-------------------------	--------------------------------------	---------------

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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 presented on the last day the Subject Diary was completed?: N O	Initial Entry

090177e196ae30b8\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: 11291032 **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-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site SW Reaction:: EL LI NG	Initial Entry

090177e196ae30b8\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: 11291032 **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?:	
--	--	--	---	--

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAI	Initial Entry

090177e196ae30b8\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: 11291032 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	
--	--	------------------	--	--

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 12:06:53 (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
Sep-21-2020 12:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 16:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 16:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 16:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 16:51:40	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b8\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:** 11291032**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-23-2020 16:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 16:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPC03 : L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 16:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC03L	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: 11291032 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Sep-23-2020 16:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPC03 : K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 16:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPC03K	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-23-2020 16:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPC03J	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 16:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BPC03J	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-23-2020 16:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID BLD0X : T	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 16:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BLD0XT	Initial Entry

5.e

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

Sep-23-2020 16:56:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID BLD0X : V	Initial Entry
---	-----------------	-----------------------------------	---	---------------

5.e Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 16:56:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BLD0XV	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-22-2020 09:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-22-2020 09:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-22-2020 09:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (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
Mar-01-2021 10:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fatigue	Initial Entry

4. Start Date Time:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/25/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (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
Mar-01-2021 10:44:36 (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
Mar-01-2021 10:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (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
Mar-01-2021 10:44:36 (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
Mar-01-2021 10:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-01-2021 10:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (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
Mar-01-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vomiting	Initial Entry

4. Start Date Time:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/25/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (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
Mar-01-2021 11:04:54 (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
Mar-01-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (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
Mar-01-2021 11:04:54 (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
Mar-01-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (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
Mar-01-2021 11:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: generalized body ach e	Initial Entry

4. Start Date Time:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/31/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (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
Mar-01-2021 11:06:45 (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
Mar-01-2021 11:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (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
Mar-01-2021 11:06:45 (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
Mar-01-2021 11:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (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
Mar-01-2021 11:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: chills	Initial Entry

4. Start Date Time:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/25/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (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
Mar-01-2021 11:30:31 (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
Mar-01-2021 11:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (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
Mar-01-2021 11:30:31 (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
Mar-01-2021 11:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (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
Mar-01-2021 11:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mild fever	Initial Entry

4. Start Date Time:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/25/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (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
Mar-01-2021 11:32:10 (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
Mar-01-2021 11:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (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
Mar-01-2021 11:32:10 (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
Mar-01-2021 11:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (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
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: worsened degenerative joint disease left shoulder	Initial Entry

4. Start Date Time:

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/17/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-02-2021 03:01:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE worsened degenerative joint disease left shoulder: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

090177e196ae30b8\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: 11291032

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

			Did this serious event result in death? NO	
			Did this serious event require or prolonged hospitalization? YES	
			Did this serious event result in persistent or significant disability/incapacity? NO	
			Is this serious event life threatening? NO	
			Other medically important serious event NO	

8. Is this adverse event the result of a study Medication Error?

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (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
Mar-01-2021 11:41:25 (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 <i>If Other, specify:</i> degenerative joint disease	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (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
Mar-01-2021 11:41:25 (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?:

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

090177e196ae30b8\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, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 11:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-02-2021 03:01:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021195295	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 15:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Dec/30/2020	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-12-2021 15:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-12-2021 15:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-12-2021 15:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willin g to return for Vacci nation 3 Participant is: eligible per local /national recom mendations and	Initial Entry

090177e196ae30b8\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: 11291032 **Subject Initials:** ---

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

			confirmed to have received only placebo at Vaccination 1/2	
--	--	--	--	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291032

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 10:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 15:05:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-20-2021 04:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing SWAB PFE and SAMP TRK forms or else clarify. Thank you.
Jan-12-2021 15:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-12-2021 15:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Con- sent Obtained Jan/4/2021	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-12-2021 15:39:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-12-2021 15:39:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-12-2021 15:39:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-22-2021 15:02:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-22-2021 15:02:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-22-2021 15:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 15:02:29	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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.
Jan-22-2021 15:02:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-22-2021 15:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BLB4Z : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLB4Z0	Initial Entry

5.b

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-22-2021 15:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BLB4Z : 1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLB4Z1	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-22-2021 15:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRL3S : J	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRL3SJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-22-2021 15:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRL3S : K	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRL3SK	Initial Entry

5.e

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Jan-22-2021 15:03:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID BRL3S : L	Initial Entry
---	-----------------	-----------------------------------	---	---------------

5.e Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:03:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BRL3SL	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-22-2021 15:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-22-2021 15:04:18 (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
Jan-22-2021 15:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 15:04:18	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

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.
Jan-22-2021 15:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-22-2021 15:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRL3P D: W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRL3PW	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: VACCINATION - 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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-12-2021 15:42:20 (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
Jan-12-2021 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-12-2021 15:42:20 (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
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Jan-12-2021 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/4/2021 15:55	Initial Entry
---	-----------------	---------------------	--	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-12-2021 15:42:20 (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
Jan-12-2021 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-12-2021 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-12-2021 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-12-2021 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Jan-12-2021 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry
---	-----------------	-----------------------------------	---------------------------	---------------

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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-12-2021 15:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-12-2021 15:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291032

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 15:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Jan/25/2021	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-26-2021 09:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 09:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 14:08:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-28-2021 04:12:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001
Visit: V102_VAX4
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1129
Site Name: (1129) Jacksonville Center for Clinical Research
Subject No: 11291032
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.
Jan-26-2021 09:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-26-2021 09:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 14:08:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRMX0 D: S	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-04-2021 14:08:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BRMX0S	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1129

Subject No: 11291032

Generated By: (b) (4)

Form: VACCINATION - 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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-25-2021 15:36:34 (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
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021 13:16	Initial Entry
---	-----------------	------------------	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-25-2021 15:36:34 (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
Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Jan-25-2021 15:36:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: YES	Initial Entry
---	-----------------	--	---------------------------	---------------

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291032

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 03:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	per data updated.
Mar-09-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-09-2021 02:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291032

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

				visit at visit 103.
Mar-08-2021 18:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/22/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Mar-08-2021 18:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-08-2021 18:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/22/2021	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical
Research

Subject No: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-09-2021 14:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/22/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-09-2021 14:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREAT MENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-09-2021 14:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Sep-22-2020 09:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-03-2020 12:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-03-2020 12:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-09-2021 07:01:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

090177e196ae30b8\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: 11291032

Subject Initials: ---

Generated By: (b) (4)

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

Mar-08-2021 18:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Mar-08-2021 00:46:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: V103 overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as Not Done with form level comment. If subject is no longer in the trial, complete the Disposition FUP form & Disposition-Treatment(EOT2)
Mar-02-2021 03:02:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 13:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-24-2021 03:46:32	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021195295

090177e196ae30b8\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: 11291032

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)		worsening degenerative joint disease left shoulder was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-22-2020 09:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry
Aug-03-2020 12:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/3/2020	Initial Entry
Aug-03-2020 12:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/3/2020	Initial Entry

090177e196ae30b8\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: 11291032

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Sep-11-2020 11:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30b8\Final\Final On: 01-Apr-2021 04:14 (GMT)