

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:54

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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 Jul/29/2020
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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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11291005]
2.	Birth Date:	(b) (6) /1970
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:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

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	Jul/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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: ---

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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
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

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Header Text: c4591001

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Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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
2.l	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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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	Jul/29/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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/1980
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	Mar/UNK/2020
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[constipation]
	Start Date:	May/UNK/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hemorrhoids]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Roux-en-Y gastric bypass]
	Start Date:	Mar/20/2020
	Ongoing:	NO End Date: Mar/20/2020

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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 f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fatty Liver Disease]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vitamin B12 deficiency]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1 h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[vitamin D deficiency]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[nearsighted]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[macular dystrophy left eye]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291005

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: ---

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1 k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hole in Retina]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right Carpal tunnel syndrome]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetic neuropathy]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1 n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sleep apnea]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[dermatitis of the scalp]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Trigger finger]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[type ii diabetes mellitus]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High cholesterol]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[overweight]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right bundle branch block]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ST depression]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	Jan/UNK/2019
	Ongoing:	YES
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[vasectomy]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[repaired hole in retina]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.y	Line/MH Number:	[25]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[smoker]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: Mar/UNK/2020

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1129

Subject No: 11291005

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:	Jul/29/2020
2.	Weight:	[229.6]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[36.0]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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 :	Jul/29/2020
2.	Randomization Number:	[40184]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/29/2020
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	[BP5PV2]
5.b	Sample ID	[BP5PV4]
5.c	Sample ID	[BP5PV3]
5.d	Sample ID	[BLD15B]
5.e	Sample ID	[BLD159]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jul/29/2020
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	[BP5PPH]
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291005

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:	Jul/29/2020 14:29
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

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/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1129

Subject No: 11291005

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/18/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/18/2020
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	[BMB575]
-----	-----------	----------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291005

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/18/2020 16:12
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

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (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: 11291005

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/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[sample documented under COVID illness visit occurred at the same time as a scheduled visit]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN698D]
5.b	Sample ID	[BN698F]
5.c	Sample ID	[BN698G]
5.d	Sample ID	[BLD18P]
5.e	Sample ID	[BLD18R]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

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/18/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/18/2021
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	[BTZPLN]
5.b	Sample ID	[BTZPL7]
5.c	Sample ID	[BTZPL8]
5.d	Sample ID	[BSFMXG]
5.e	Sample ID	[BSFMXH]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Aug/10/2020

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: 11291005

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/10/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONTACT OUTCOME
Aug/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEHEALTH VISIT
2.	Was contact made?	YES Date of Contact: Aug/10/2020
3.	Comments:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

eCRF Audit Trail History

Signs and Symptoms

1.	Date of Assessment:	Aug/10/2020
2.	Date of First Symptom Started:	Aug/9/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Aug/21/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Aug/10/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV28744]
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Self swab acquired see self swab ECRF page]

Aliquot

Please enter barcode for each aliquot.

5-a	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Aug/10/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1. DELETED	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Aug/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

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

Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 17-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.		[]			Sponsor-Defined Identifier	Test :	Result :	Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 17-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Lab Chemistry Details

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

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 17-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 17-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 17-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Aug/10/2020

Form Version: 17-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 17-Jul-2020 21:54

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	//
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Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Aug/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Oct/19/2020

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: 11291005

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	Oct/19/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/19/2020
2.	Date of First Symptom Started:	Oct/19/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/3/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[increased nasal congestion]
-----	------------------------	------------------------------

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Symptoms - Other Text:

[wife tested positive for covid-19]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/19/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

Microbiology Specimen

1.	Actual Date of Collection:	Oct/19/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[CV17493]
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **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: 11291005

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Self Swab taken]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Oct/19/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 17-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test :	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 17-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

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

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 17-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 17-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 17-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Oct/19/2020

Form Version: 17-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	//
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Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 17-Jul-2020 21:54

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Oct/19/2020

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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.	Start Date:	//
6.	Ongoing?	

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING
Oct/19/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Sep/15/2020

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: 11291005

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/15/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Sep/15/2020

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: 11291005

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/15/2020
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	[BN698D]
5.b	Sample ID	[BN698F]
5.c	Sample ID	[BN698G]
5.d	Sample ID	[BLD18P]
5.e	Sample ID	[BLD18R]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Nov/17/2020

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: 11291005

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	Nov/17/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Nov/17/2020

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: 11291005

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: Nov/17/2020
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	[BMPP3C]
5.b	Sample ID	[BMPP3D]
5.c	Sample ID	[BR6XZ8]
5.d	Sample ID	[BR6XZ7]
5.e	Sample ID	[BR6XZ6]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

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: 11291005

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/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

Form: UNPLANNED VISIT

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

Form: CONTACT OUTCOME - UNPLANNED

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/10/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

Form: VITAL SIGNS - TEMP

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ []	Comments
	Unit:	Not Done _____ _____	Comments
	Temperature Location:	Not Done _____ _____	Comments

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/20/2020

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: 11291005

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/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/20/2020

Form: UNPLANNED VISIT

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/20/2020

Form: CONTACT OUTCOME - UNPLANNED

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/20/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[]

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: 11291005

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/15/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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. DELETED	ADVERSE EVENT	1	headache	Jul/29/2020 14:12	NO End Date Time: Jul/29/2020 14:22	Repeating Pages
2.	ADVERSE EVENT	2	bowel obstruction	Jan/21/2021 UNK: UNK	NO End Date Time: Jan/22/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Internal Hernia	Jan/21/2021 10:55	NO End Date Time: Jan/22/2021 UNK:UNK	Repeating Pages

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Jul/29/2020 14:12
5.	Is the adverse event still ongoing?	NO End Date Time: Jul/29/2020 14:22
6.	Toxicity Grade:	+
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
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[bowel obstruction]
4.	Start Date Time:	Jan/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? 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: [unknown]

[Comments](#)

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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 WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021087081]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Internal Hernia]
4.	Start Date Time:	Jan/21/2021 10:55
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [etiology previous surgery]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021087081]

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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Medication Error

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

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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 Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

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: 11291005

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: 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: 11291005

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?	

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT

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

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

Subject No: 11291005 **Subject Initials:** ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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/15/2021
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/15/2020

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: 11291005

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: 11291005

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: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Oct-07-2020 17:16:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	sample documented under COVID illness visit occurred at the same time as a scheduled visit

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
8	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
9	Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Aug-26-2020 15:54:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Self swab acquired see self swab ECRF page. Not applicable
Form	Aug-26-2020 15:52:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
Aug/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

Item	Date	User	Comment
2	Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
Aug/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

Item	Date	User	Comment
3	Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

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Item	Date	User	Comment
4	Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
Aug/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

Item	Date	User	Comment
5	Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
5	Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
5	Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

Item	Date	User	Comment
6	Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
6	Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
6	Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

Form: VITAL SIGNS - TEMP - Comments

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	Alex Hill (b) (4)	Per note no fever. Patient visit conducted via telephone. Not Done
Form	Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	Alex Hill (b) (4)	Per note no fever. Patient visit conducted via telephone. <hr/> Not Done
1	Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 1

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	Alex Hill (b) (4)	Per note no fever. Patient visit conducted via telephone. <hr/> Not Done
2.a	Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	Alex Hill (b) (4)	Per note no fever. Patient visit conducted via telephone. <hr/> Not Done
2.a	Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 1

Form Version: 21-Aug-2020 02:51

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	Alex Hill (b) (4)	Per note no fever. Patient visit conducted via telephone. <hr/> Not Done
2.a	Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

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

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
7	Mar-09-2021 13:22:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Critical findings were found on the CT Scan 1/21/21 at 15:14, surgical team contacted same day on 1/21/21. Patient was brought to the OR urgently and surgery note completed by 19:00. Urgent intervention indicated

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-02-2021 16:26:54 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Michael Koren	Approved	Nov-25-2020 13:47:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-23-2020 17:13:35 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Koren	Approved	Nov-01-2020 11:55:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Oct-29-2020 13:00:12 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

Michael Koren	Approved	Oct-29-2020 08:25:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Koren	Approved	Oct-28-2020 11:20:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Oct-28-2020 11:00:24 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Koren	Approved	Oct-14-2020 09:37:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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.

Alex Hill	N/A	Oct-06-2020 19:05:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Koren	Approved	Sep-16-2020 13:25:44 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Sep-15-2020 12:46:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Michael Koren	Approved	Sep-01-2020 16:20:12 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Aug-31-2020 15:04:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

N/A

Michael Koren	Approved	Aug-26-2020 20:12:37 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:54

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jul-29-2020 15:17:11 (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
Jul-29-2020 15:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Jul-29-2020 15:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jul/29/2020	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Jul-29-2020 15:17:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11291005	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1970	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jul-29-2020 15:20:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jul-29-2020 15:20:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:20:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Jul-29-2020 15:21:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

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I.a

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: 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?: Criterion ID: IN01A00 Use only:	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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 (dependent upon study stage)	Initial Entry

I.a Criterion met?

Date	Location	User	Value	Reason
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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: 2 Criteria: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures Criteria met?: YES Criterion ID: (For Pfizer use only): IN02A00	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

I.b Inclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

I.b Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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

I.b Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: 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	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

			Criteria ID: IN03A00 (For Pfizer use only):	
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I.c Inclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 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?: Criterion ID: (For Pfizer use only): EX01A00	Initial Entry

2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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)

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

2.b Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 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	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

			Criteria ID: EX03A00 (For Pfizer use only):	
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2.c Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe adverse reaction as associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Receipt of medications intended to prevent COVID-19	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

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Subject Initials: ---

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			Criterion met NO ?: Criterion ID: EX04A00 (For Pfizer use only):	
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

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Header Text: c4591001

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Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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			Criteria Description: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination Criteria met?: NO Criteria ID: (For Pfizer use only): EX08A00	
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2.e Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

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Header Text: c4591001

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Form Version: 17-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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 Printer use only): EX10A00	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

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Site No: 1129

Subject No: 11291005

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

2.f Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (EX11A00 For Pfizer use only):	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

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

2.g Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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: EX12A00 (For Pfizer use only):	Initial Entry

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Header Text: c4591001

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Subject No: 11291005

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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2.h Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criteria on Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study Criteria on met?: NO	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

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			Criteria ID: EX14A01 (For Pfizer use only):	
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2.j Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

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2.k				
Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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: (Former Pfizer use only): EX15A01	Initial Entry

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Subject No: 11291005

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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)

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion 17 Number: Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: NO Criterion ID: (For Pfizer use only): EX16A01	Initial Entry

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Header Text: c4591001

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Subject No: 11291005

Generated By: (b) (4)

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2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 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	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

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			Criteria ID: (For Pfizer use only): EX21A01	
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2.m Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (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
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jul-29-2020 15:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-29-2020 15:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

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I.a

Date	Location	User	Value	Reason
Jul-31-2020 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number 1 : Medical History Term: Seasonal Allergies Start Date: UNK/UNK/1980 Ongoing: YES	Transcription Error
Jul-29-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History Term: Seasonal Allergies Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Seasonal Allergies	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Transcription Error
Jul-29-2020 15:26:32 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

(US & Canada)		(b) (4), (b) (6)	
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I.a Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Jul-31-2020 09:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 2 Medical History Term: Gastroesophageal reflux disease Start Date: Mar/UNK/2020 Ongoing: YES	Transcription Error
Jul-29-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Gastroesophageal reflux disease Start Date: Mar/3/2020 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastroesophageal reflux disease	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 09:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/UNK/2020	Transcription Error
Jul-29-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2020	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Jul-29-2020 15:33:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: constipation Start Date: May/UNK/2020 0 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:33:06 (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
Jul-29-2020 15:33:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: constipation	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:33:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/UNK/2020	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:33:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Jul-29-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Hemorrhoids Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemorrhoids	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Jul-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Roux-en-Y gastric bypass Start Date: Mar/20/2020 Ongoing: NO End Date: Mar/20/2020	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Roux-en-Y gastric bypass	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/20/2020	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/20/2020	Initial Entry

I.f

Date	Location	User	Value	Reason
Jul-29-2020 15:36:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Fatty Liver Disease Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11291005

Generated By: (b) (4)

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

I.f Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:36:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:36:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatty Liver Disease	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:36:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:36:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Jul-29-2020 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History T Vitamin B12 defic erm: iency Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Vitamin B12 deficiency	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2018	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Jul-29-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 8 Medical History Term: vitamin D deficiency Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

I.h Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vitamin D deficiency	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Jul-29-2020 15:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: nearsighted Start Date: UNK/UNK/1970 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

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Subject No: 11291005

Generated By: (b) (4)

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Subject Initials: ---

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I.i Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nearsighted	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1970	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.j

Date	Location	User	Value	Reason
Jul-29-2020 15:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 r: Medical History: macular dystrophy Term: left eye Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

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I.j Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: macular dystrophy left eye	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
Jul-29-2020 15:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: hole in Retina Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

1.k Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:41:04 (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
Jul-29-2020 15:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hole in Retina	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Jul-29-2020 15:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History: right Carpal tunnel syndrome Term: syndrome Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11291005

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right Carpal tunnel syndrome	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Jul-29-2020 15:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term: Diabetic neuropathy Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11291005

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

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

I.m Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetic neuropathy	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.n

Date	Location	User	Value	Reason
Jul-29-2020 15:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: Sleep apnea Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

I.n Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sleep apnea	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.o

Date	Location	User	Value	Reason
Jul-29-2020 15:44:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 15 : Medical History Term: dermatitis of the scalp Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.o Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:44:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:44:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: dermatitis of the scalp	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:44:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:44:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.p

Date	Location	User	Value	Reason
Jul-29-2020 15:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: Trigger finger Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.p Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Trigger finger	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:45:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.q

Date	Location	User	Value	Reason
Jul-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 17 : Medical History T type ii diabetes m erm: ellitus Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.q Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: type ii diabetes mellitus	Initial Entry

I.q Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.q Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:46:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.r

Date	Location	User	Value	Reason
Jul-29-2020 15:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 Medical History Term: High cholesterol Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

L.r Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: High cholesterol	Initial Entry

L.r Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

L.r Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

L.s

Date	Location	User	Value	Reason
Jul-29-2020 15:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 19 Medical History Term: overweight Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.s Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 19	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> overweight	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1995	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.t

Date	Location	User	Value	Reason
Jul-29-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 20 r: Medical History right bundle branch block Term: Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1129

Subject No: 11291005

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

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1.t Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:50:18 (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
Jul-29-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right bundle branch block	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:50:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.u

Date	Location	User	Value	Reason
Jul-29-2020 15:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 21 Medical History Term: ST depression Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.u Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ST depression	Initial Entry

I.u Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.u Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.v

Date	Location	User	Value	Reason
Jul-29-2020 15:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 22 Medical History Term: anxiety Start Date: Jan/UNK/2019 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.v Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: anxiety	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2019	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.w

Date	Location	User	Value	Reason
Jul-29-2020 15:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 23 Medical History Te rm: vasectomy Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.w Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 15:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 15:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vasectomy	Initial Entry

I.w Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.w Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 15:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

I.x

Date	Location	User	Value	Reason
Jul-31-2020 09:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 24 : Medical History Term: repaired hole in retina Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

I.x Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 09:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 24	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 09:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> repaired hole in retina	Initial Entry

I.x Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 09:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2019	Initial Entry

I.x Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 09:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.y

Date	Location	User	Value	Reason
Jul-31-2020 09:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 25 Medical History Term: smoker Start Date: UNK/UNK/2002 Ongoing: NO End Date: Mar/UNK/2020	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

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

1.y Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 09:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 09:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: smoker	Initial Entry

1.y Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 09:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2002	Initial Entry

1.y Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 09:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/UNK/2020	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Jul-29-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jul-29-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 229.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jul-29-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jul-29-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 67.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jul-29-2020 15:54:48 (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
Jul-29-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 36.0	Initial Entry

7.a

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1129

Subject No: 11291005

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

Date	Location	User	Value	Reason
Jul-29-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 99.5 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-29-2020 15:54:48 (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
Jul-29-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-29-2020 15:54:48 (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
Jul-29-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Jul-29-2020 15:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-05-2020 04:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-03-2020 14:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-03-2020 14:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 40184	Transcription Error
Aug-03-2020 08:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM QUERY: Randomization number is recorded as 11291005; however, it is recorded as 40184 in IMPALA. Please review and reconcile.
Jul-29-2020 15:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11291005	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Jul-29-2020 15:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-29-2020 15:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-30-2020 07:21:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jul-30-2020 05:16:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-29-2020 15:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-29-2020 15:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-30-2020 07:21:55	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Sample ID: BP5PV2	
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5.a Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 07:21:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5PV2	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-30-2020 07:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP5PV4	scanned removed last letter to match label
Jul-30-2020 07:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP5PV4F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 07:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jul-30-2020 07:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5PV4	scanned removed last letter to match label
Jul-30-2020 07:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Jul-30-2020 07:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5PV4F	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-30-2020 07:30:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP5PV3	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 07:30:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5PV3	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-30-2020 07:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLD15B	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 07:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLD15B	Initial Entry

5.e

Date	Location	User	Value	Reason
Jul-30-2020 07:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLD159	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 07:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLD159	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Jul-29-2020 15:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-29-2020 15:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-30-2020 07:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jul-30-2020 05:17:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-29-2020 15:56:16 (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.
Jul-29-2020 15:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-30-2020 07:39:31	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

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

Sample ID: BP5PPH

5.a Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 07:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5PPH	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jul-29-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jul-29-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jul-29-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-05-2020 10:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-04-2020 20:01:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-04-2020 20:01:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: Jul/29/2020 14:29	Transcription Error
Aug-04-2020 00:30:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per eDiary records, e-Diary Temperature value(s) recorded is (< 94 F). Please confirm if the thermometer recording from subject or the entry is appropriate. Thanks.

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291005

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

Jul-29-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020 13:55	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-29-2020 15:56:55 (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
Jul-29-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jul-29-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jul-29-2020 15:56:55 (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
Jul-29-2020 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jul-29-2020 15:57:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-18-2020 16:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/18/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (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-19-2020 11:53:11 (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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IGU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO :	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (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-19-2020 11:53:11 (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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (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-19-2020 11:53:11 (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-19-2020 11:53:11 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4), (b) (6)	ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
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2.d Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

2.f

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (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-19-2020 11:53:11 (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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE PA IN	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-19-2020 11:53:11 (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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE D JOINT PAIN Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D 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-19-2020 11:53:11 (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
Aug-19-2020 11:53:11	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

(autocalc)

DELTOID MUSCLE

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS Were injection site reactions p NO resent on the last day the Subj ect Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLIN G Were injection site reactions NO present on the last day the Su bject Diary was completed?:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (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-19-2020 11:53:11 (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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 11:53:11 (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-19-2020 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/18/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-18-2020 16:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.6 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-18-2020 16:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-18-2020 16:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-18-2020 16:12:15 (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-18-2020 16:12:15 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1129

Subject No: 11291005

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

(US & Canada)

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

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 17:41:58 (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-19-2020 17:41:58 (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-19-2020 17:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 17:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 17:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 17:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMB575	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 17:42:06	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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)

BMB575

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/18/2020 16:12	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291005

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

Date	Location	User	Value	Reason
Aug-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION 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-18-2020 16:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 01:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Closed as per site response.
Oct-08-2020 13:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-08-2020 07:08:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4906657;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_A1. Please review for duplication and update as appropriate.
Sep-15-2020 12:46:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Sep/15 /2020	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (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-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (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-15-2020 12:48:12 (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-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IGU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO :	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (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-15-2020 12:48:12 (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-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DAC HE Were fever or systemic sympt oms present on the last day th e Subject Diary was complete d?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (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-15-2020 12:48:12 (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-15-2020 12:48:12 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4), (b) (6)	ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
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2.d Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

2.f

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (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-15-2020 12:48:12 (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-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED 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-15-2020 12:48:12 (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-15-2020 12:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD 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-15-2020 12:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (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-15-2020 12:48:12 (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-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions p NO resent on the last day the Subj ect Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLIN G Were injection site reactions present on the last day the Su bject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN AT INJECTI ON SIT E Were injection site reactio ns present on the last day the Subject Diary was co mpleted?: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-15-2020 12:48:12 (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-15-2020 12:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-15-2020 16:11:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-15-2020 16:11:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 01:53:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-08-2020 13:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Oct-08-2020 09:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-08-2020 09:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-08-2020 09:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Transcription Error
Oct-08-2020 06:38:37 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	DM query present

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Oct-08-2020 06:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Thanks for response. As scheduled visit occurs at the same time as a COVID illness visit, 'Sample Collected' should be 'No'. Kindly review and update appropriately.
Oct-08-2020 03:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 17:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-07-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 13:11:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Per CCG, sample should be documented under COVID illness visit if visit occurs at the same time as a scheduled. Please consider to remove the sample barcodes from this visit and consider to add an item level comment. Thank you.
Sep-15-2020 16:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 16:11:46 (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.

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Sep-15-2020 16:11:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-08-2020 13:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sample documented under COVID illness visit occurred at the same time as a scheduled visit	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 17:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN698D	Transcription Error (DELETED)
Sep-15-2020 16:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN698D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 17:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN698D	Transcription Error (DELETED)
Oct-07-2020 13:12:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	re-queried
Oct-07-2020 10:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-07-2020 03:43:21 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4906542; This Barcode is already recorded more than

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				once (for the same subject). Please review and update as appropriate.
Sep-15-2020 16:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN698D	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 17:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN698E	Transcription Error (DELETED)
Sep-15-2020 16:12:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN698F	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 17:18:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BN698F	Transcription Error (DELETED)
Oct-07-2020 13:12:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Clo sed	re-queried
Oct-07-2020 10:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Ans wered	Original value is correct
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 1: Ope ned	DMW4906683;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Sep-15-2020 16:12:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BN698F	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 17:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6)	Data Entry: Sample ID: BN698G	Transcription Error (DELETED)
Sep-15-2020 16:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6)	Data Entry: Sample ID: BN698G	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 17:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BN698G	Transcription Error (DELETED)
Oct-07-2020 13:12:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Clo sed	re-queried
Oct-07-2020 10:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Ans wered	Original value is correct
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 1: Ope ned	DMW4906684;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Sep-15-2020 16:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BN698G	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-07-2020 17:18:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: Sample ID: BLD18P	Transcription Error (DELETED)
Sep-16-2020 12:57:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: Sample ID: BLD18P	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 17:18:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD18P	Transcription Error (DELETED)
Oct-07-2020 13:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	re-queried
Oct-07-2020 10:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4906540;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Sep-16-2020 12:57:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLD18P	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-07-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLD18R	Transcription Error (DELETED)
Sep-16-2020 12:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLD18R	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BLD18R	Transcription Error (DELETED)
Oct-07-2020 13:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Clo sed	re-queried
Oct-07-2020 10:11:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Ans wered	Original value is correct
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 1: Ope ned	DMW4906541;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Sep-16-2020 12:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BLD18R	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-24-2021 13:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-24-2021 13:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-24-2021 13:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 13:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 13:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-24-2021 13:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-24-2021 13:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BTZPLN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:20:09	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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)

BTZPLN

5.b

Date	Location	User	Value	Reason
Feb-24-2021 13:20:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BTZPL7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:20:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPL7	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-24-2021 13:20:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BTZPL8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:20:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BTZPL8	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-24-2021 13:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFMXG	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFMXG	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.e

Date	Location	User	Value	Reason
Feb-24-2021 13:20:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSFMXH	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 13:20:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSFMXH	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 Form: DATE OF VISIT - ILLNESS ONSET - 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 10:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-06-2020 19:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Query 3: Answered	Data collected from 15SEP2020 Visit 3 was duplicated to Convalescent eCRF.
Oct-06-2020 09:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical Query: Please complete convalescent visit as requested.
Oct-05-2020 17:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Query 3: Answered	Subject completed Visit 2 on 18AUG2020 and Visit 3 on 15SEP2020. Duplicate data that was collected at those visits can be transcribed into a Convalescent visit eCRF if required by data management. All symptoms were confirmed as resolved at Visit 3.
Sep-28-2020 15:04:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Query: Per protocol, CONVALESCENT Visit must take place 28 to 35 days after COVID Illness Visit, please clarify if CONVA visit has been completed. If not, please complete as soon as possible.
Sep-02-2020 02:53:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - 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: 11291005 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Sep-01-2020 15:13:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Query 2: Answered	See Unplanned Contact eCRF for Ediary Illness contact for 20AUG2020. Two separate entries.
Aug-28-2020 06:18:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	eDiary: Per eDiary records, EDIARY ILLNESS DATE is 20Aug2020, however DOV illness visit 10Aug2020 is before that. Please verify and update appropriately. Else, clarify. Thanks
Aug-21-2020 15:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-20-2020 16:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-12-2020 08:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: Per CRF CRs Section 8.26, please complete COVID TEST, SWAB PFE, HLTHCARE, and ILL POTEN forms.
Aug-11-2020 15:58:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Aug-11-2020 15:58:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

Date	Location	User	Value	Reason
Aug-11-2020 15:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEHEALTH VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Aug-11-2020 15:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/9/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-28-2020 13:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-28-2020 11:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-28-2020 11:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Aug/21/2020	Transcription Error
Oct-28-2020 09:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Convalescent visit occurred but Date of Last Symptom Resolved is missing. Please confirm symptoms are still ongoing. If symptoms have resolved update response for Symptom ongoing as 'No' and add date resolved.
Aug-11-2020 15:59:38	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

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)	YES	
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4.a

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED S s: HORTNESS OF BREAT H Symptom NO Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291005**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**4.d Symptoms:**

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Aug-11-2020 15:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291005**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Aug-20-2020 16:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Aug-20-2020 15:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not done
Aug-17-2020 19:06:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Item incomplete

2. Specimen Type:

Date	Location	User	Value	Reason
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

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

6. Trade Name:

Date	Location	User	Value	Reason
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Aug-20-2020 15:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-11-2020 16:00:49 (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-11-2020 16:00:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 04:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Aug-14-2020 13:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-14-2020 13:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Aug-14-2020 13:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/10/2020	Transcription Error
Aug-12-2020 04:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Opened	Please provide Date of Collection.
Aug-12-2020 04:39:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-11-2020 16:00:49 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				barcodes are entered. Please review and correct as appropriate.
Aug-11-2020 16:00:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-14-2020 13:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV28744	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 04:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Aug-20-2020 16:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-20-2020 13:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4312229;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Aug-14-2020 13:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV28744	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Aug-26-2020 20:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Aug-20-2020 16:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Aug-20-2020 16:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Aug-20-2020 09:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Aug-17-2020 19:06:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Item incomplete

2. Sample Type

Date	Location	User	Value	Reason
Aug-20-2020 16:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Aug-20-2020 16:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Aug-20-2020 09:40:15 (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-20-2020 16:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-20-2020 16:50:08 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Sample Collected?' is marked as No and 'If

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1129**Subject No:** 11291005**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

(US & Canada)				no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Aug-20-2020 16:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Aug-20-2020 16:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-20-2020 09:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 09:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 09:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/10/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Aug-20-2020 16:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-20-2020 16:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Self swab acquired see self swab EC RF page	Transcription Error
Aug-20-2020 16:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **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: 11291005 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

				the field and re-enter without adding extra spaces or using enter or tab keys.
Aug-20-2020 16:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Self swab acquired see self swab EC RF page.	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 16:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Aug-20-2020 16:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Aug-20-2020 09:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV28744	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data deleted
Aug-21-2020 06:06:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Data deleted
Aug-20-2020 16:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Aug-20-2020 16:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020

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

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Site Name: (1129) Jacksonville Center for Clinical Research

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Generated By: (b) (4)

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Aug-20-2020 16:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-20-2020 13:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW4312228;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Aug-20-2020 09:41:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-20-2020 09:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Aug-20-2020 09:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV28744	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner EMERGENC : Y ROOM Occurrence of Visits NO or Contacts:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291005**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291005**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.f

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
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Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Con NO tacts:	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 13:10:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Audit Trail
Aug/10/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

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Date	Location	User	Value	Reason
Aug-20-2020 15:35:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Aug-21-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-17-2020 19:06:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Item incomplete

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

(US & Canada)		(b) (4), (b) (6)		
Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Aug-20-2020 15:36:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-20-2020 15:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
Aug/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

Aug-19-2020 18:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Aug-14-2020 13:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Aug-14-2020 13:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-21-2020 15:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Aug-20-2020 16:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Aug-20-2020 16:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
Aug-19-2020 09:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per CRF CRs Section 8.31.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptoms of "new or increased cough" and "diarrhea."
Aug-19-2020 09:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Opened in error.
Aug-16-2020 12:07:38 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Item incomplete

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/10/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)

(b) (4),

(b) (6)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - 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:** 11291005**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
Oct-28-2020 11:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-28-2020 11:05:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-28-2020 11:05:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-28-2020 11:05:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291005**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-28-2020 11:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-19-2021 02:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 17:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-18-2021 17:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Nov/3/2020	New Information
Feb-15-2021 06:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM:Please confirm the symptoms are still ongoing for this

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

				COVID Illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify. Thanks
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom s: NEW OR INCREASED S HORTNESS OF BREAT H Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW LOSS OF TAST E OR SMELL Symptom Present: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291005**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25**4.h Symptoms:**

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-28-2020 11:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-28-2020 11:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: increased nasal congestion	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Oct-28-2020 11:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: increased nasal congestion	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-29-2020 13:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - wife tested positive fo Other: r covid-19	Transcription Error (DELETED)
Oct-28-2020 11:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - wife tested positive fo Other: r covid-19	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-29-2020 16:20:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 13:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: wife tested positive for covid-19	Transcription Error (DELETED)
Oct-29-2020 13:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-29-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: As this is not a symptom, please remove.
Oct-28-2020 11:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: wife tested positive for covid-19	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Oct/19/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

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090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-28-2020 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NALT Unknown	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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:** 11291005**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
Oct-28-2020 11:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-28-2020 11:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-28-2020 11:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 11:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 11:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-28-2020 11:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV17493	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 11:08:18	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 11291005

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)

CV17493

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-28-2020 12:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-28-2020 12:06:36 (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
Oct-28-2020 12:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-28-2020 12:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Self Swab taken	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner EMERGENC : Y ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1129**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject No:** 11291005**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 11:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Oct/19/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-28-2020 12:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-28-2020 12:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-28-2020 11:10:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History on Sep/15/2020**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:** 11291005**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
Oct-09-2020 04:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-08-2020 09:19:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-08-2020 07:08:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW4906656;The Date of Visit at Visit COVID_A1 is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-06-2020 19:05:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry : Sep/1 5/202 0	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-06-2020 19:05:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Sep/15/2020 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-06-2020 19:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-06-2020 19:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 11:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 3: Closed	Will raise post clarification.
Oct-13-2020 11:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 3: Opened	LIMS Query: As per Lab all the samples below are received for visit V3_MONTH1_POSTVAX2_L. Kindly submit SCF so that visit can be changed to CONVALESCENT visit in Lab.
Oct-13-2020 11:04:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Closed	New query will be raised.
Oct-13-2020 11:01:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Opened	LIMS Query: As per Lab all the samples below are received for visit V3_MONTH1_POSTVAX2_L. Kindly submit SCF so that visit can be changed to COVID_A1 in Lab.
Oct-06-2020 19:09:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001
Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
 on Sep/15/2020 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: 11291005 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:25

Oct-06-2020 19:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-06-2020 19:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-06-2020 19:09:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Sample ID: BN698D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 13:12:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-07-2020 10:10:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4906537;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-06-2020 19:09:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: BN698D	Initial Entry

5.b

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Sep/15/2020 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-06-2020 19:09:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Sample ID: BN698F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 13:13:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-07-2020 10:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4906538;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-06-2020 19:09:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: BN698F	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-06-2020 19:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Sample ID: BN698G	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Sep/15/2020 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 13:13:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-07-2020 10:11:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4906539;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-06-2020 19:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: BN698G	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-06-2020 19:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Sample ID: BLD18P	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Sep/15/2020 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 13:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-07-2020 10:10:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	please advise if labs taken for visit3 can also apply to convalescent visit as they happened on the same day. If not, then no labwork done
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4906535;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-06-2020 19:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: BLD18P	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-06-2020 19:10:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Sample ID: BLD18R	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Sep/15/2020 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 13:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-07-2020 10:09:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please advise if labs taken for visit3 can also apply to convalescent visit as they happened on the same day. If not, then no labwork done
Oct-07-2020 03:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4906536;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-06-2020 19:10:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: BLD18R	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History on Nov/17/2020

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-23-2020 17:13:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/17/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-23-2020 17:13:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/17/2020 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:** 11291005**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
Nov-23-2020 17:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-23-2020 17:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-23-2020 17:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-23-2020 17:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-23-2020 17:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-23-2020 17:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMPP3C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 17:14:19	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History on Nov/17/2020

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: 11291005

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)	BMPP3C	
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5.b

Date	Location	User	Value	Reason
Nov-23-2020 17:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMPP3D	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 17:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPP3D	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-23-2020 17:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6XZ8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 17:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6XZ8	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-23-2020 17:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6XZ7	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 17:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6XZ7	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/17/2020 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

5.e

Date	Location	User	Value	Reason
Nov-23-2020 17:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6XZ6	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 17:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6XZ6	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 15:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

Form: UNPLANNED VISIT - 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Sep-16-2020 07:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-15-2020 13:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry
Sep-15-2020 13:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-15-2020 13:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	no missing item viewable, form appears complete, please be explicit in form where missing item is located.
Sep-15-2020 09:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Kindly update the missing item. Thank you.
Aug-31-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry
Aug-31-2020 15:10:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-31-2020 15:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 15:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-31-2020 15:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/10/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Sep-01-2020 15:15:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-01-2020 15:15:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: YES Date of Contact: Aug/10/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Transcription error. Sub-investigator kept scheduled visit. No unscheduled visit in-clinic required.
Sep-01-2020 07:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Aug-31-2020 15:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

Form Version: 22-Apr-2020 21:04

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

Aug-31-2020 15:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Aug/10/2020 Contact Outcome: VISIT ARRANGED	Initial Entry
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Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/10/2020**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:** 11291005**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**I. Date:**

Date	Location	User	Value	Reason
Sep-01-2020 20:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_VS001_06
Sep-01-2020 15:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Query 1: Answered	Patient visit was conducted via telephone. Vital signs not done.
Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Not Done	Initial Entry
Sep-01-2020 05:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4425122;Vitals Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Record Identifier:: Not Applicable Temperature: Not Done Temperature Unit: Not Done Temperature Location:: Not Done	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Temperature: Not Applicable Temperature Unit: Not Applicable Temperature Location:: Not Applicable	Initial Entry
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2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Not Done	Initial Entry
Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Not Done	Initial Entry
Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 15:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Alex Hill (b) (4)	Data Entry: Not Done	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/10/2020

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

Aug-31-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/20/2020

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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-20-2020 16:24:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/20/2020

Form: UNPLANNED VISIT - 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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Aug-20-2020 16:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-20-2020 16:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/20/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

Date	Location	User	Value	Reason
Aug-20-2020 16:26:01 (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
Aug-20-2020 16:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Aug/20/2020 Contact Outcome: VISIT NOT REQUIRED, INVEST IGATOR DECISION	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (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: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-16-2020 10:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-16-2020 10:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-16-2020 10:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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

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Date	Location	User	Value	Reason
Aug-03-2020 13:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	per query and rvw'd with Lead coordinator/Nurse//ba
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Mar-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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

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1. Category:

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (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
Jul-29-2020 16:04:35 (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
Aug-03-2020 23:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-03-2020 13:33:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	per query and rvw'd with Lead coordinator/Nurse//ba
Jul-30-2020 11:52:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	e-Diary: AE 'Headache' on 29-Jul-20 seems to be same as e-Diary occurrence 'Headache' reported on '29-Jul-20'. Please reconcile or confirm in the query response as appropriate
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020 14:12	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time: Jul/29/2020 14:22	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Jul-29-2020 16:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-29-2020 16:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Jul-29-2020 16:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (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-09-2021 20:49:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-09-2021 10:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Mar-09-2021 10:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bowel obstruction	New Information
Mar-09-2021 04:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2021087081, the term was reported as 'bowel obstruction' due to internal hernia'. Please consider to update the term to bowel obstruction since internal hernia was already recorded as a separate event.
Feb-24-2021 15:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-24-2021 14:48:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1129**Subject No:** 11291005**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1129) Jacksonville Center for Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-24-2021 12:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-24-2021 12:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bowel obstruction due to internal hernia	Transcription Error
Feb-21-2021 20:58:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021087081 Internal hernia(onset date:21Jan2021)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
Feb-17-2021 12:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	FUP was confirmed sent today.
Feb-16-2021 19:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thanks for confirming. No FUP has been noted.
Feb-11-2021 14:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	FUP SAE being filed with medications
Feb-07-2021 04:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL (AER# 2021087081) Per report, "the subject was not taking Medication". However, multiple conditions have been listed on MedHx CRF. Pls clarify. Thanks.
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bowel obstruction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

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Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/22/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-10-2021 15:11:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 14:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see note per subinvestigator. Critical findings were found on the CT Scan 1/21/21 at 15:14, surgical team contacted same day on 1/21/21. Patient was brought to the OR urgently and surgery note completed by 19:00. Urgent intervention indicated
Mar-09-2021 13:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: A Bowel obstruction is usually not a life threatening AE, please clarify why this is considered life threatening. There is no changed data per your response.
Mar-09-2021 10:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-09-2021 10:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: A Bowel obstruction is usually not a life threatening AE, please clarify why this is considered life threatening.

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Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-09-2021 10:51:08 (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 Did this serious event result in death ? NO Did this serious event require or pro long hospitalization? YES Did this serious event result in persi stent or significant disability/incapa city? NO Is this serious event life threatening? NO Other medically important serious e vent NO	Transcription Error
Feb-04-2021 07:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE bowel obstruction: Response

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Generated By: (b) (4)

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(US & Canada)				to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
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Feb-03-2021 13:48:52 (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 Did this serious event result in death? NO Did this serious event require or pro long hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
 If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (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
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Subject Initials: ---

Generated By: (b) (4)

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Feb-11-2021 12:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Closed	GPD Clin: Thank you. I will close query now. Please update when discharge summary becomes available.
Feb-08-2021 16:37:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	hospital records requested, narrative from subject
Feb-05-2021 16:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Opened	GPD Clin: Per the SAE report, the cause of the bowel obstruction was the prior Roux En Y gastric bypass surgery. Please consider adding that as the relationship.
Feb-03-2021 13:54:54 (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> unknown	Transcription Error
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 15:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-17-2021 12:52:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	FUP SAE filed today with requested information
Feb-13-2021 08:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thanks for confirming, would you provide updates so I can close the query?
Feb-08-2021 16:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	records requested
Feb-07-2021 04:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL_ In the safety report submitted to safety no information on clinical presentation, workup (including imaging) and final diagnosis on discharge has been provided. Pls submit a FU form with the missing details of hospital course. Thanks
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 13:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED WITH S EQUELAE	Initial Entry

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

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Date	Location	User	Value	Reason
Feb-03-2021 13:56:40 (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
Feb-04-2021 07:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021087081	Initial Entry

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Subject No: 11291005

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Mar-02-2021 15:50:08 (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-02-2021 15:50:08 (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-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Internal Hernia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021 10:55	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/22/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-09-2021 13:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Mar-09-2021 13:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-09-2021 13:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Transcription Error
Mar-09-2021 10:32:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Internal Hernia is usually not a life threatening AE, please clarify why this is considered life threatening.
Mar-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-10-2021 12:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Candidate	SAE Team please check if SAE number is valid as 'is event serious' is NO. Thank you!
Mar-09-2021 17:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Internal Hernia: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Mar-09-2021 17:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Mar-09-2021 03:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Mar-08-2021 12:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Mar-08-2021 12:45:56 (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 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	Transcription Error
Mar-03-2021 23:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thanks for your response. Unfrozen per response, kindly review and update.
Mar-03-2021 10:25:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 15:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please unfreeze AE "Bowel Obstruction due to internal hernia" for update. Bowel

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				obstruction and internal hernia are separate AE terms
Mar-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Mar-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Internal Hernia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	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-02-2021 15:50:08 (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-02-2021 15:50:08 (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> etiology previous surgery	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Mar-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-02-2021 15:50:08 (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-02-2021 15:50:08 (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-02-2021 15:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED WITH S EQUELAE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 15:50:08 (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-03-2021 10:25:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021087081	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-02-2021 16:26:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Feb-02-2021 16:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 16:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-02-2021 16:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-02-2021 16:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-02-2021 16:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDIT IONAL VACCINATION	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1129

Subject No: 11291005

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1129) Jacksonville Center for Clinical Research

Subject Initials: ---

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

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I. Subject Status

Date	Location	User	Value	Reason
Feb-09-2021 15:43:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-03-2021 14:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-01-2021 09:49:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_ A SAE report has been submitted to safety (AER#2021087081), but missing on SDB. Please revise and update AElog accordingly. Thank.
Sep-16-2020 10:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jul-29-2020 15:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jul-29-2020 15:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Sep-16-2020 10:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry
Jul-29-2020 15:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/29/2020	Initial Entry
Jul-29-2020 15:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/29/2020	Initial Entry

090177e196ae30ae\Final\Final On: 01-Apr-2021 04:13 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1129

Site Name: (1129) Jacksonville Center for Clinical Research

Subject No: 11291005

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Aug-25-2020 19:40:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry