

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[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 Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jul/30/2020
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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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11331006]
2.	Birth Date:	(b) (6)/1957
3.	Sex:	MALE
4.	Ethnicity:	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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[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

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Form Version: 30-Jul-2020 21:27

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Jul/30/2020
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:** 1133**Subject No:** 11331006**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Disease]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Open Heart Surgery]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Colectomy Hartman]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Strock (CVA)]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign Prostate Hyperplasia]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Congestive Hearth Failure (CHF)]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Ischemic colitis]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bipolar Disorder]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Schizophrenia with paranoia]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ETOH abuse]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2018

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/30/2020
2.	Weight:	[112.0]
3.	Unit:	kg
4.	Height:	[179.0]
5.	Unit:	cm
6.	Body Mass Index:	[35.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.2]
	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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jul/31/2020
2.	Randomization Number:	[220755]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/31/2020
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	[BNB4TW]
5.b	Sample ID	[BNB4TX]
5.c	Sample ID	[BNB4TY]
5.d	Sample ID	[BPFS04]
5.e	Sample ID	[BPFS05]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jul/31/2020
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	[BNB52H]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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/31/2020 10:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[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

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
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: 21-Aug-2020 02:51

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/21/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY1S0]
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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/21/2020 11:11
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/5/2020
2.	Erroneous Visit	

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[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

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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 WORSENER MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENER 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:	RIGHT
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

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[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:	[The blood was unable to draw due to the subject was dehydrated.]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1133 **Site Name:** (1133) QPS-MRA, LLC

Subject No: 11331006 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Worsening Bipolar Disorder	Aug/24/2020 08:00	NO End Date Time: Sep/4/2020 14:00	Repeating Pages
2.	ADVERSE EVENT	2	Urinary tract infection	Oct/5/2020 10:00	NO End Date Time: Oct/14/2020 10:00	Repeating Pages
3.	ADVERSE EVENT	3	Syncope	Oct/5/2020 10:00	NO End Date Time: Oct/5/2020 10:00	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening Bipolar Disorder]
4.	Start Date Time:	Aug/24/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/4/2020 14:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: [Psychiatric illness]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020336469]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urinary tract infection]
4.	Start Date Time:	Oct/5/2020 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 10:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
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

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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: [Escherichia coli]
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
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020387703]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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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)	[Syncope]
4.	Start Date Time:	Oct/5/2020 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/5/2020 10:00
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: [Urinary tract Infection]

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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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	[]

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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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:	//

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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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?	

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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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?	

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Vital Signs

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

Vital Signs Details

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

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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?	

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Contact Outcome

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

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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/15/2021
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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/22/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/22/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/22/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/22/2021
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	[BR4ZMJ]
5.b	Sample ID	[BSFD64]
5.c	Sample ID	[BSFD65]

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/22/2021
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	[BR4ZM7]
-----	-----------	----------

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/22/2021 10:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
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	[BRKJ99]
-----	-----------	----------

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/12/2021 09:47
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/5/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[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, Signed, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b)(6)	Approved	Mar-11-2021 12:13:24 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, (b)(6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-22-2021 14:01:35 (UTC-05:00) Eastern Time (US & Canada)	(b)(4), (b)(6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b)(6)	Approved	Mar-11-2021 12:13:24 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, (b)(6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b)(6)	N/A	Dec-29-2020 10:57:16 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Howard Schwartz	Approved	Nov-04-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HowardSchwartz, 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-23-2020 08:09:43 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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, Signed, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Howard Schwartz	Approved	Oct-22-2020 14:38:50 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HowardSchwartz, 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-20-2020 14:49:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Howard Schwartz	Approved	Oct-13-2020 22:07:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HowardSchwartz, 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-13-2020 15:28:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Howard Schwartz	Approved	Oct-13-2020 10:14:40 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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, Signed, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Affidavit:

By my dated signature below, I, HowardSchwartz, 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-05-2020 16:13:46 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Howard Schwartz	Approved	Sep-23-2020 19:39:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b)(6)	N/A	Sep-21-2020 13:28:08 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Howard Schwartz	Approved	Sep-16-2020 14:50:31 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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, Signed, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Affidavit:

By my dated signature below, I, HowardSchwartz, 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 16:29:49 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Howard Schwartz	Approved	Sep-15-2020 14:29:58 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HowardSchwartz, 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-02-2020 07:43:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b)(6)	Approved	Sep-01-2020 15:42:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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, Signed, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Affidavit:

By my dated signature below, I, (b)(6), 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.

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jul-31-2020 11:37:05 (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-31-2020 11:37:05 (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: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Consent Was:

Date	Location	User	Value	Reason
Jul-31-2020 11:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Jul/30/2020	Initial Entry

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1133**Subject No:** 11331006**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Sep-02-2020 07:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Closed	confirmed event added in AE CRF
Sep-01-2020 14:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Data was updated
Sep-01-2020 07:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	SAE RECON:AER# 2020336469 worsening bipolar(onset date:24Aug2020)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.
Jul-31-2020 11:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11331006	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jul-31-2020 11:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1957	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: MALE	Initial Entry

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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

4. Ethnicity:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 11:38:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: WHITE	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Date of Visit

Date	Location	User	Value	Reason
Jul-31-2020 11:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jul/30/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1.a

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Inclus 1 ion N umbe r: Crite Male or female participa rion nts between the ages of Descr 18 and 55 years, inclusi ption ve, 65 and 85 years, incl : usive, or 18 and 85 year s, inclusive, at randomiz ation (dependent upon st udy stage) Crite YES rion met?: Crite IN01A00 rion I D: (F or Pfi zer us e only):	Initial Entry

1.a Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Male or female participants bet ween the ages of 18 and 55 year	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			s, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	
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I.a Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: IN01A00	Initial Entry

I.b

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Inclusion Number: : Criterion Definition: 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	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			Criterion ID : (For Pfizer use only): IN02A00	
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1.b Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: IN02A00	Initial Entry

1.c

Date	Location	User	Value	Reason
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

<p>Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b)(6)</p>	<p>Data Entry: Inclusion Number: 3 Criteria: 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: IN03A00 Use only: (For Pfizer use only):</p>	<p>Initial Entry</p>
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1133**Site Name:** (1133) QPS-MRA, LLC**Subject No:** 11331006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34***I.c Inclusion Number:***

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Inclus 4 ion Nu mber:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			<p>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</p> <p>Criterion met?: YES</p> <p>Criterion ID: IN04A00</p> <p>Use only: (For Pfizer use only):</p>	
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1133**Site Name:** (1133) QPS-MRA, LLC**Subject No:** 11331006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**1.d Inclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclu 1 sion N umbe r:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			<p>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</p> <p>Criterion Met?: NO</p> <p>Criterion ID: EX01A00</p> <p>Use only: (For Pfizer)</p>
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclusion Number: Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: Criterion ID: (For Pfizer use only): EX02A00	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

2.b Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclusion Number: 3	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			<p>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)</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX03A00</p> <p>Use only: (For Pfizer use only):</p>	
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1133**Site Name:** (1133) QPS-MRA, LLC**Subject No:** 11331006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**2.c Exclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: History of severe adverse reaction associated with a vaccine and /or severe allergic reaction (eg. a naphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclusion Number: Criterion D description: Receipt of medications intended to prevent COVID-19	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			Criterion m NO et?: Criterion I EX04A00 D: (For Pfizer use only) :	
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclus 8 ion Nu	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			<p>mber:</p> <p>Criteria Immunocompromised individuals with known on Des or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p>Criteria NO</p> <p>on met</p> <p>?:</p> <p>Criteria EX08A00</p> <p>on ID:</p> <p>(For Pfizer use only</p> <p>):</p>	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1133**Site Name:** (1133) QPS-MRA, LLC**Subject No:** 11331006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclusion Number: 10	Initial Entry

Header Text: c4591001

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Site Name: (1133) QPS-MRA, LLC

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Generated By: (b) (4)

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			<p>Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX10A00</p> <p>Use only: (For Pfizer use only):</p>	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1133**Site Name:** (1133) QPS-MRA, LLC**Subject No:** 11331006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**2.f Exclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			Criterion met NO ?: Criterion ID: EX11A00 (For Pfizer use only):	
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclusion Number: 12	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: EX12A00 (For Pfizer use only):	
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

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

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

Exclusion Number: 13

Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids

Criterion met?: NO

Criterion ID: (Former Pfizer only): EX13A01

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Site No: 1133

Site Name: (1133) QPS-MRA, LLC

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Subject Initials: ---

Generated By: (b) (4)

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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclusion Number: 15	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			<p>Criteria Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p>Criteria Met?: NO</p> <p>Criteria ID: EX14A01 (For Pfizer use only)</p>	
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Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

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2.j Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: EX14A01	Initial Entry

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Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

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2.k				
Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Exclusion Number: 16 Criterion: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation Criterion met?: NO Criterion ID: EX15A01 (For Pfizer use only):	Initial Entry

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Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Participation in other studies in volving study intervention withi n 28 days prior to study entry an d/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Exclusio 17 n Numb er:	Initial Entry

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			<p>Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles</p> <p>Criterion met?: NO</p> <p>Criterion ID: (For Pfizer use only): EX16A01</p>	
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Header Text: c4591001

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2.l Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> 17	Initial Entry

2.l Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Previous participation in other studies involving study interventions containing lipid nanoparticles	Initial Entry

2.l Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Exclusion Number:	Initial Entry

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			<p>Criterion D 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</p> <p>Criterion D Met?: NO</p> <p>Criterion D Exclusion Code: EX21A01</p> <p>Criterion D (For Pfizer use only):</p>	
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Header Text: c4591001

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Site No: 1133

Site Name: (1133) QPS-MRA, LLC

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Generated By: (b) (4)

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2.m Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (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-31-2020 11:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: EX21A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jul-31-2020 11:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jul/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-31-2020 11:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1.a

Date	Location	User	Value	Reason
Jul-31-2020 11:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Coronary Artery Disease Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 14:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Sep-15-2020 12:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Medical history was updated
Sep-14-2020 07:22:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Med Hx of subject has been updated in SDB, recording: (CABG)in 2009 and in 2013, CHF from 2012 and ongoing, CVA in 2014, among other items. Please revise/update accordingly.

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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Jul-31-2020 11:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Coronary Artery Disease	Initial Entry
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I.a Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 11:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2008	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 11:49:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-15-2020 12:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH Num 2 ber: Medical Histor Open Heart S y Term: urgery Start Date: UNK/UNK/20 09 Ongoing: NO End Date: UNK/UNK /2009	Transcription Error
Sep-15-2020 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH Num 2 ber: Medical Histor Open Heart S y Term: urgery Start Date: UNK/UNK/20 08	Transcription Error

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			Ongoing: NO End Date: UNK/UNK /2009	
Jul-31-2020 11:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Open Heart Surgery Start Date: UNK/UNK/2009 Ongoing: NO End Date: UNK/UNK /2009	Initial Entry

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Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.b Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:54:47 (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-31-2020 11:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Open Heart Surgery	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2009	Transcription Error
Sep-15-2020 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2008	Transcription Error
Jul-31-2020 11:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/2009	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 11:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2009	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-16-2020 14:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH Num 3	Transcription Error

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Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

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Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			ber: Medical Histor Colectomy Ha y Term: rtman Start Date: UNK/UNK/20 17 Ongoing: NO End Date: UNK/UNK /2017	
Sep-15-2020 16:30:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH N 3 umber: Medical His Colectomy Hart tory Term: man/Ileostomy Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/20 17	Transcription Error
Sep-15-2020 16:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH N 3 umber: Medical His Colectomy Hart tory Term: man/Ileostomy Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/19 66	Transcription Error
Sep-15-2020 12:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH N 3 umber: Medical His Colectomy Hart tory Term: man/Ileostomy Start Date: UNK/UNK/1966	Transcription Error

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Header Text: c4591001

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Subject No: 11331006

Generated By: (b) (4)

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			Ongoing: NO End Date: UNK/UNK/1966	
Aug-11-2020 07:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	Data Entry: Line/MH Number: 3 Medical History Term: Endo cholecystectomy Start Date: UNK/UNK/1966 Ongoing: NO End Date: UNK/UNK/1966	Transcription Error
Aug-10-2020 14:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	Data Entry: Line/MH Number: 3 Medical History Term: Endo colstectomy Start Date: UNK/UNK/1966 Ongoing: NO End Date: UNK/UNK/1966	spelling
Aug-05-2020 11:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH Number: 3 Medical History Term: Enterocolostomy Start Date: UNK/UNK/1966 Ongoing: NO End Date: UNK/UNK/1966	Changed Information

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

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Jul-31-2020 11:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: end colostomy Start Date: UNK/UNK/1966 Ongoing: NO End Date: UNK/UNK/1966	Initial Entry
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Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

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I.c Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:57:25 (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
Sep-16-2020 18:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 5: Clo sed	Discrepancy has been closed.
Sep-16-2020 14:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: An swere d	Transcription Error
Sep-16-2020 14:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry : Colect omy Hartm an	Transcription Error
Sep-16-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 4: Clo sed	Response satisfies query
Sep-16-2020 01:58:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 5: Op ened	Multiple concepts in the term COLECTOMY HARTMAN/ILEOSTOMY. Split the term into COLECTOMY HARTMAN and ILEOSTOMY and report

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				as 2 separate entries. Thank you.
Sep-15-2020 16:30:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 4: Answered	Changed data per query
Sep-15-2020 12:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 4: Opened	GPDClin: 1) The participant has a MHx of ischemic colitis 2017, was this procedure performed for that? If yes, please correct the time to 2017. 2) the initial entry was "endocholecystectomy" 1966, should "cholecystectomy" 1966 a separate MHx item?
Sep-15-2020 12:41:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 3: Closed	Response satisfies query
Sep-15-2020 12:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Sep-15-2020 12:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry : Colectomy Hartman/Ileostomy	Transcription Error
Sep-14-2020 15:52:43 (UTC-05:00)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 3: Opened	GPDClin: 1) Please add the missing psychiatric MHx: bipolar affective disorder,

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Eastern Time (US & Canada)				paranoid schizophrenia; or, Schizoaffective disorder, etc. 2) Based on the missing MHx, please re-assess eligibility against Inclusion #3 and Exclusion #1.
Aug-11-2020 19:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.
Aug-11-2020 10:19:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Reissued: Opened	Please confirm it was "cholecystectomy" without "endo" as Laparoscopic cholecystectomy was not available in 1966 when this procedure was performed.
Aug-11-2020 07:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Aug-11-2020 07:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	Data Entry : Endo cholecystectomy	Transcription Error
Aug-11-2020 04:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Aug-10-2020 18:15:32 (UTC-05:00) Eastern Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Clarify ENDO COLSTECTOMY as follows...Term is unclear. Are you reporting ENDO

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Generated By: (b) (4)

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(US & Canada)				CHOLECYSTECTOMY? Or COSTECTOMY? Or other? Please update the verbatim term to clarify. Thank you.
Aug-10-2020 14:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	spelling
Aug-10-2020 14:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	Data Entry	spelling : Endocolsteatomy
Aug-10-2020 08:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (b) (4)	Query 1: Reissued: Opened	Please specify what information has changed. Thank you.
Aug-05-2020 11:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-05-2020 11:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry	Changed Information : Enterocolosomy
Aug-03-2020 17:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (b) (4)	Query 1: Opened	Clinical review: Per CRF completion requirements (8.6), when a surgery or interventional procedure is recorded, the condition that led to the surgery/procedure MUST

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				be recorded as a separate entry. Please evaluate and take appropriate action.
Jul-31-2020 11:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry : end c olosto my	Initial Entry

Header Text: c4591001

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I.c Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 16:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2017	Transcription Error
Jul-31-2020 11:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: UNK/UNK/1966	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 16:30:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-15-2020 16:30:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2017	Transcription Error
Sep-15-2020 16:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Term Colectomy Hartman/Ileostomy End Date is prior to Start Date.
Jul-31-2020 11:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO End Date: UNK/UNK/1966	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-15-2020 12:24:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Strock (CVA)	Initial Entry

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Header Text: c4591001

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			Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2014
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1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:24:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 12:24:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Strock (CVA)	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:24:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2014	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:24:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-15-2020 12:26:25	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: c4591001

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(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH Number: ber: Medical History Term: Benign Prostate Hyperplasia Start Date: UNK/UNK/2012 Ongoing: YES
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:26:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 12:26:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Benign Prostate Hyperplasia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:26:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> UNK/UNK/2012	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:26:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-15-2020 12:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 6 :	Initial Entry

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Subject No: 11331006

Generated By: (b) (4)

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			Medical History T Hypertension erm: Start Date: UNK/UNK/2008 Ongoing: YES
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I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:27:10 (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
Sep-15-2020 12:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Hypertension	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2008	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-15-2020 12:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History T Hyperlipidem erm: ia	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			Start Date:	UNK/UNK/2008	
			Ongoing:	YES	

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 12:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Hyperlipidemia	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2008	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-15-2020 12:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Congestive Heart Failure (CHF) Start Date: UNK/UNK/2012	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			Ongoing: YES	
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I.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:54 (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
Sep-15-2020 12:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Congestive Hearth Failure (CHF)	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2012	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-15-2020 12:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 9 er: Medical History Ischemic colitis Term: Start Date: UNK/UNK/20 17	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			Ongoing:	NO	
				End Date:	
				UNK/UNK/2017	

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 12:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Ischemic colitis	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2017	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-15-2020 16:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Line/MH Number: 10	Transcription Error

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			Medical History Term: Bipolar Disorder Start Date: UNK/UNK/2018 Ongoing: YES	
Sep-15-2020 12:31:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Bipolar Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:31:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Clos ed	Response satisfies query
Sep-16-2020 15:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Ans wered	This symptoms occurred for the first time on 24Aug2020
Sep-16-2020 10:25:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reis sued:Opened	GPDClin: please address my query that if any suicide attempts and/or ideations occurred in the past? If yes, please add it as a separate MHx item.
Sep-16-2020 05:52:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Clos ed	Discrepancy has been closed.
Sep-15-2020 16:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Transcription Error
Sep-15-2020	ACV0PFEINFP6000	auto query	Query 1: Ans	Transcription

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

16:31:32 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)	were d	Error
Sep-15-2020 16:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Bipolar Disorder	Transcription Error
Sep-15-2020 15:06:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Clarify BIPOLAR as follows...The term appears truncated. Are you reporting BIPOLAR DISORDER? BIPOLAR PACEMAKER INSERTION? If so, edit. Otherwise clarify. Thank you.
Sep-15-2020 13:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if any suicide attempts and/or ideations occurred in the past. If yes, please add it as a separate MHx item.
Sep-15-2020 12:31:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Bipolar	Initial Entry

I,j Start Date:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Sep-15-2020 12:31:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2018	Initial Entry
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

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Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1133) QPS-MRA, LLC

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I.j Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:31:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
Sep-15-2020 12:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 11 ber: Medical History Term: Schizophrenia with paranoia Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

I.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 17:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Sep-16-2020 14:42:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Subject stable. Able to continue in the study. Approved by PI.
Sep-16-2020 10:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Opened	GPDClin: Thank you! I understand that those are missing MHx not reported by the participant at enrollment. My question is that retrospectively, if PI knew those at enrollment, would he consider the subject eligible based on (In#3 and Ex#1).
Sep-15-2020 16:33:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	This data came with the medical record that was requested due to the SAE.
Sep-15-2020 13:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: As those unreported MHx (Bipolar, Schizophrenia, alcohol abuse) became available,

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

				along with other MHx in GI and CV, please provide PI's retrospective assessment on eligibility, particularly against Inclusion#3 and Ex#1.
Sep-15-2020 12:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Schizophrenia with paranoia	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2018	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Sep-15-2020 12:35:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 12 er: Medical History ETOH abuse Term: Start Date: UNK/UNK/2000 Ongoing: NO End Date: UNK/UNK/2018	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:35:23 (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
Sep-15-2020 12:35:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ETOH abuse	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:35:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: UNK/UNK/2000	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:35:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date:

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jul/30/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 112.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 179.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.0	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Record Identifier 1 : Temperature: 98.2 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (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-31-2020 11:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-31-2020 11:47:45 (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-31-2020 11:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Randomization Date :

Date	Location	User	Value	Reason
Jul-31-2020 11:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Jul/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jul-31-2020 11:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: 220755	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Jul-31-2020 11:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-31-2020 11:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 15:51:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-04-2020 07:38:42 (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-31-2020 11:46:39 (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-31-2020 11:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Jul/31/2020	Initial Entry

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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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a

Date	Location	User	Value	Reason
Aug-05-2020 15:51:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BNB4TW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 15:51:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BNB4TW	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-05-2020 15:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BNB4TX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 15:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BNB4TX	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-05-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BNB4TY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 15:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BNB4TY	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.d

Date	Location	User	Value	Reason
Aug-05-2020 15:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPFS04	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 15:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BPFS04	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-05-2020 15:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPFS05	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 15:58:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BPFS05	Initial Entry

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1133**Subject No:** 11331006**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jul-31-2020 11:46:27 (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-31-2020 11:46:27 (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-01-2020 12:48:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-31-2020 11:46:27 (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-31-2020 11:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of Collection: Jul/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-01-2020 12:48:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BNB52H	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 12:48:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BNB52H	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-11-2020 04:30:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Per site confirmation
Aug-10-2020 14:24:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	Query 1: Answered	Changed data per query
Aug-10-2020 09:30:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Opened	DM Requery #3: Thank you for response. Please consider to update item level comment to specify the reason for 1 day delay. As the "appointment is not qualified as a temporary delay of vaccination (refer protocol section 5.5. Else clarify.
Aug-07-2020 13:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	There is no option available for delay, options available do not apply.
Aug-06-2020 07:29:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Reissued:Opened	DM Requery # 2: Thanks for updating the response for delay of vaccination however form or item level comment for reason for 1 day delay is still not reported on eCRF.Please consider to record form or item level comment for reason

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

				for delay.
Aug-05-2020 15:26:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Aug-05-2020 15:26:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Changed Information
Aug-05-2020 05:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Opened	DM Review: Please response to "Was there a temporary delay of vaccination?" is marked as "No" and update the reason for 1 day delay in a form or item level. As "appointment is not qualified as a temporary delay of vaccination (refer protocol section 5.5.
Jul-31-2020 11:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	Subject was unable to complete visit on 07/30/2020, due to an appointment. Approval from sponsor to give vaccination to subject on 07/31/2020.
Jul-31-2020 11:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Reason(s) for Temporary Delay of Vaccination' is not entered. Please review and update as appropriate.

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

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Subject Initials: ---

Generated By: (b) (4)

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Jul-31-2020 11:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: YES Date of First Delay: Jul/30/2020	Initial Entry
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2. Treatment Name

Date	Location	User	Value	Reason
Jul-31-2020 11:43:20 (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-31-2020 11:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-18-2020 21:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Aug-14-2020 09:39:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	VISIT WAS SPLIT BETWEEN JUL 30 AND JUL 31. CONSENT SIGNED ON JULY 30TH AND RANDOMIZED ON THE 31ST.
Aug-13-2020 19:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	Temperature collected date on vital signs CRF and vaccination date are different. Please review dates and

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1133**Subject No:** 11331006**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

				update as appropriate or otherwise clarify.
Aug-12-2020 09:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Per site confirmation
Aug-12-2020 08:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-12-2020 08:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry : Jul/31/2020 10:08	Transcription Error
Aug-11-2020 11:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4173108;Dose Start Date is before the Randomization Date. Please review and update as appropriate.
Aug-10-2020 14:23:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	Data Entry : Jul/30/2020 10:08	Transcription Error
Jul-31-2020 11:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry : Jul/31/2020 10:08	Initial Entry

5. Anatomical Location:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Jul-31-2020 11:43:20 (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
Jul-31-2020 11:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jul-31-2020 11:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jul-31-2020 11:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 11:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-10-2020 06:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Per site confirmation
Aug-07-2020 09:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-07-2020 09:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES - REACTOGENICITY E- DIARY COLLECTED FOR T HIS SUBJECT	Changed Information
Aug-07-2020 01:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	DM Query: Patient is expected to be included in the Reactogenicity subset. Please review and update as appropriate
Jul-31-2020 11:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-21-2020 11:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Aug/21/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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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-21-2020 11:57:32 (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-21-2020 11:57:20 (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?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (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-21-2020 11:57:20 (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-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

			GU E	
			Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	NO

2.b Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 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-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

2.c Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (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-21-2020 11:57:20 (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-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.e

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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

2.f Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (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-21-2020 11:57:20 (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-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

2.h

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR WORSE NED JOINT P AIN	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-21-2020 11:57:20 (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-21-2020 11:57:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RIGHT	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-21-2020 11:57:20 (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-21-2020 11:57:20 (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-21-2020 11:57:20 (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-21-2020 11:57:20 (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-21-2020 11:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date:

Date	Location	User	Value	Reason
Aug-21-2020 11:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Aug/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-21-2020 11:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier: 1 : Temperature: 98.0 Temperature Unit F : Temperature Loca ORAL CAV tion:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-21-2020 11:51:40 (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-21-2020 11:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-21-2020 11:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: F	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-21-2020 11:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 11:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 11:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-22-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 11:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 11:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Aug/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-22-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPY1S0	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BPY1S0	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-21-2020 11:51:21 (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-21-2020 11:51:21 (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-21-2020 11:51:21 (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-21-2020 11:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Aug/21/2020 11:11	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-21-2020 11:51:21 (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-21-2020 11:51:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)		(b) (4)	
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7. Route:

Date	Location	User	Value	Reason
Aug-21-2020 11:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-21-2020 11:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 11:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 07:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	As per site confirmation - updated PD tracker
Oct-06-2020 12:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Subject came out of window due to a scheduled ileostomy reversal surgery. A protocol deviation was performed.
Oct-06-2020 07:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (10 day) from DOV (21/Aug /2020) at V2_VAX2_L. Please reconcile and update accordingly, else confirm date is correct as is.
Oct-05-2020 16:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/5/2020	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary w as completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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

2.b Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

2.c Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

2.f Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR WORSE NED MUSC LE 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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

2.h

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (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
Oct-05-2020 16:15:38 (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
Oct-05-2020 16:15:38 (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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RIGHT	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 16:15:38 (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
Oct-05-2020 16:15:38 (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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 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
Oct-05-2020 16:15:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Oct-05-2020 16:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-05-2020 16:18:33 (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-05-2020 16:18:33 (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-05-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-05-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: The blood was unable to draw due to the subject was dehydrated.	Transcription Error
Oct-05-2020 16:18:33 (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

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

				the field and re-enter without adding extra spaces or using enter or tab keys.
Oct-05-2020 16:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: The blood was unable to draw due to the subject was dehydrated.	Initial Entry

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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-07-2020 09:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/5/2020	New Information
Sep-21-2020 13:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Aug/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-21-2020 13:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-21-2020 13:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Sep-01-2020 14:41:03 (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
Oct-23-2020 11:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Deleted	Query is invalid or does not apply
Oct-20-2020 10:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Candidate	DM: Site request to update form. Do not issue query. Form can be re-locked after update is made and terms coded.
Sep-01-2020 14:41:03 (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
Sep-20-2020 11:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Term in SDB updated to worsening of bipolar disorder. issue resolved.
Sep-17-2020 10:06:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued: Candidate	SAE RECON 4: The term in SDB still shows as worsening bipolar/acute psychosis/suicidal ideation. Please submit a follow up AEM form to update term to only WORSENING BIPOLAR DISORDER in

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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				Safety database.
Sep-16-2020 17:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Ans wered	A new SAE form was created in order to clarify the term: Worsening of Bipolar Disorder.
Sep-16-2020 12:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Clo sed	Response satisfies query
Sep-16-2020 07:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 2: Rei ssued: Opene d	SAE RECON 3: The term in SDB was reported as worsening bipolar/acute psychosis/suicidal ideation. Please submit a follow up AEM form to update term to only WORSENING BIPOLAR DISORDER in Safety database.
Sep-15-2020 12:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Ans wered	Suicidal ideation and acute psychosis are symptoms of the worsening bipolar disorder
Sep-15-2020 12:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Ans wered	Medical history is updated
Sep-13-2020 20:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Rei ssued: Opene d	Medical History is now unfrozen; please enter history of bipolar disorder as noted in SAE.
Sep-12-2020	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS	Query	Discrepancy has been

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Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Subject Initials: ---

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03:29:50 (UTC-05:00) Eastern Time (US & Canada)		Oracle (b) (4)	6: Clo sed	closed.
Sep-12-2020 00:29:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 3: Clo sed	Another query raised to enter two separate event.
Sep-12-2020 00:28:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 2: Rei ssued: Opene d	SAE RECON2: To match safety database, kindly update SUICIDAL IDEATION and ACUTE PSYCHOSIS as a separate event. Else clarify via query response. Thank you.
Sep-11-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Ans wered	Transcription Error
Sep-11-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ans wered	Transcription Error
Sep-11-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Transcription Error
Sep-11-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error

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Site No: 1133

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Generated By: (b) (4)

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Sep-11-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry : Worsening Bipolar Disorder	Transcription Error
Sep-10-2020 19:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Closed	Response satisfies query
Sep-10-2020 19:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 4: Closed	Response satisfies query
Sep-10-2020 11:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued: Opened	Medical History is now unfrozen; please enter history of bipolar disorder in Medical History.
Sep-10-2020 06:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Reissued: Opened	SAE RECON 1: Term was updated however, please consider to enter SUICIDAL IDEATION event as a separate entry.
Sep-10-2020 06:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued: Opened	SAE RECON 1: Term was updated however, please consider to enter ACUTE PSYCHOSIS event as a separate entry.
Sep-09-2020 20:54:45 (UTC-05:00) Eastern Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 6: Opened	Multiple concepts in the term WORSENING BIPOLAR DISORDER/ ACUTE

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1133**Subject No:** 11331006**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

(US & Canada)				PSYCOSIS/SUICIDAL IDEATION. Split the term into WORSENING BIPOLAR DISORDER and ACUTE PSYCOSIS and SUICIDAL IDEATION and report as 3 separate entries. Thank you.
Sep-09-2020 19:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Opened	Case has been unfrozen. Thank you.
Sep-09-2020 16:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Sep-09-2020 16:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Sep-09-2020 16:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Sep-09-2020 16:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry : Worsening Bipolar Disorder/ Acute Psycosis	New Information

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Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

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			/Suicidal Ideation	
Sep-09-2020 13:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Please unfreeze the subject to be able to update the medical history.
Sep-04-2020 13:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 4: Opened	Event term in SDB has been updated to "worsening bipolar/acute Psychosis/suicidal ideation". Updates should be reflected in InForm. Please review/update as appropriate.
Sep-04-2020 06:24:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Opened	SAE RECON:AER#2020336469 SUICIDAL IDEATION(onset date:24Aug2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-04-2020 06:24:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	SAE RECON:AER#2020336469 ACUTE PSYCHOSIS(onset date:24Aug2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-02-2020 15:04:27 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	In the SAE submitted to safety, participant had a medical history of bipolar disorder. Please update

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Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)				MEDHX in CRF accordingly.
Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry : Worse ning B ipolar Disord er	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-09-2020 13:30:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Aug/24/2020 08:00	New Information
Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Aug/24/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-09-2020 13:31:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Sep/4/2020 14:00	New Information
Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

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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
Dec-30-2020 13:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 5: Closed	Response satisfies query
Dec-29-2020 10:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Transcription Error
Dec-29-2020 10:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Is this serious event associate d 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 disabi lity/incapacity? NO Is this serious event life threat ening? NO Other medically important ser ious event	Transcription Error

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1133**Subject No:** 11331006**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

			NO	
Dec-17-2020 10:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 5: Opened	GPDClin: "Life-threatening" is selected here but not selected in SAE report. It is also inconsistent with AE grade 3. Please verify if the SAE was life-threatening. If No, de-select it. If Yes, change AE grade to 4 and submit FU SAE report accordingly.
Oct-24-2020 00:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 4: Closed	Appreciate the prompt response. Thank you.
Oct-23-2020 07:34:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 4: Answered	A follow-up SAE was sent with Covid testing result.
Oct-21-2020 11:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 4: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed during hospitalization (yes/no) and if yes, the results. Thank you.
Sep-09-2020 13:31:47 (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	New Information

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			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? YES Other medically important serious event NO	
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Subject No: 11331006

Generated By: (b) (4)

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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
Sep-02-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 3: Closed	Query was unnecessary as the site already submitted the initial SAE report.
Sep-02-2020 12:13:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 3: Opened	GPDClin: This case is not in Pfizer's SAE database now. Please report it ASAP per SAE reporting requirement.
Sep-02-2020 12:10:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Sep-02-2020 07:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 14:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	Medical Records was requested to be able to answer these questions.
Sep-01-2020 14:41:03 (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.

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Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening Bipolar Disorder: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Did this serious event require or prolong hospitalization? 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
Sep-01-2020 14:41:03 (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
Sep-01-2020 14:52:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RELATED If Not Related to study treatm ent(s), this event is due to: OTHER If Other, specify: Psychiatric illness	Transcription Error
Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RELATED If Not Related to study treatm ent(s), this event is due to: OTHER	Initial Entry

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-01-2020 14:41:03 (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
Sep-01-2020 14:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-12-2021 22:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-12-2021 08:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Subject had psychotherapy at hospital
Jan-03-2021 16:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify what was given as non-drug treatment.
Sep-01-2020 14:41:03 (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
Sep-10-2020 06:29:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 2: Closed	issue resolved
Sep-09-2020 13:32:30	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query

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(UTC-05:00) Eastern Time (US & Canada)				
Sep-09-2020 13:32:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Sep-09-2020 13:32:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RECOVERED/RESOLVED	New Information
Sep-09-2020 13:31:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Worsening Bipolar Disorder: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-04-2020 06:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	SAE RECON:AER#2020336469 ,outcome was updated to RECOVERING/RESOLVING in SAE form however, reported as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-04-2020 06:31:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	outcome updated to recovering/resolving in SDB. new query issued
Sep-02-2020 07:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020336469 ,outcome was reported to UNKNOWN in SAE form however, reported as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a

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				follow-up form.
Sep-01-2020 14:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:41:03 (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
Sep-02-2020 07:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: 2020336469	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-06-2020 15:04:32 (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
Oct-06-2020 15:04:32 (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
Oct-23-2020 15:08:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Oct-23-2020 07:39:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	All the information from medical records was transferred to the SAE form. No more specific diagnosis was made in regards to the UTI. Syncope event occurred at the site, and was just mentioned in the "History of Present Illness" at the time of admission.
Oct-22-2020 20:43:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Opened	GPDClin: 1) Please clarify if a more specific diagnosis was made in the discharge notes, e.g., cystitis, pyelonephritis, etc. 2) Please provide any significant comment in the discharge notes regarding the syncope event.

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Oct-13-2020 16:23:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Closed	follow up with safety for updates
Oct-13-2020 16:00:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Reissued:Opene d	SAE RECON: Please confirm submission of a follow up SAE form with these updates. Thanks.
Oct-13-2020 15:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-13-2020 15:28:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Urinary tract infection	New Information
Oct-13-2020 14:20:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Reissued:Opene d	Hi , Thank you for answering, If the UTI is the serious event, please update this term to Urinary Tract Infection- and consider to add Syncope as a non-serious AE. Please send safety FUP to safety as well with these updates.
Oct-13-2020 13:51:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	Query 1: Answered	the Urinary Tract Infection is the SAE the Syncope is secondary to UTI
Oct-13-2020 12:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Reissued:Opene d	SAE RECON 2: Per Safety database, SAE of Syncope and Urinary tract infection has been reported. Please consider adding Urinary tract infection as a new SAE event in a new log line. Please review and update or submit a follow up SAE form for safety updates
Oct-13-2020 11:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Can you please unlock the subject so I can change and update the term? Now it will be called a Urinary tract infection.

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Oct-13-2020 08:25:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Reissued:Open ed	SAE RECON 1:Syncope event matched with SDB data.Urinary track Infection was added as new event in Safety database.Please confirm if event should be recorded as a separate event in AE CRF. If so, please add a new form.
Oct-13-2020 07:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	I am unable to do any change in this log. Please let me update the information.
Oct-13-2020 06:55:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	SAE RECON:AER#2020387703 urinary tract infection(onset date:05Oct2020)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.
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Syncope	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/5/2020 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-20-2020 14:53:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Oct/14/2020 10:00	New Information

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Oct-13-2020 15:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	New Information
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Oct/5/2020 10:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; 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
Oct-24-2020 00:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Appreciate the prompt response. Thank you.
Oct-23-2020 07:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 3: Answered	A follow-uo SAE was sent with Covid testing result.
Oct-21-2020 11:28:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed during hospitalization (yes/no) and if yes, the results. Thank

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				you.
Oct-13-2020 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-13-2020 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Urinary tract infection: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-07-2020 05:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Syncope: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Is this serious event associated with congenital anomaly or bir th 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 disabil ity/incapacity?	Initial Entry

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			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.

Date	Location	User	Value	Reason
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-02-2020 16:53:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Oct-30-2020 10:47:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	The term was transcribed as it appears in the medical records. The correct term is ileostomy
Oct-23-2020 15:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Reissued :Opened	GPDClin: Thank you! I found reversal procedure on 9/23/20 in the updated SAE report. Would

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				you please make correction in the SAE report for "...Hartman pouch/ileostomy ...and ileostomy reversal on 23Sep2020". Should be "Colostomy" both places.
Oct-23-2020 07:46:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	On the SAE form sent on 12Oct2020 (Follow-up #3, page 5) was mentioned the colostomy reversal performed on 23Sep2020.
Oct-22-2020 20:33:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Opened	GPDClin: Per SAE report, the predisposing factor for UTI was recent colostomy reversal. Would you please clarify when the reversal was done?
Oct-13-2020 15:30:30 (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:	New Information

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			OTHER <i>If Other, specify:</i> Escherichia coli	
Oct-09-2020 11:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Puig (b) (4)	Query 1: Closed	Dehydration entry not required as AE per Clinical team
Oct-07-2020 16:06:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Dehydration]. Any symptoms, AEs or other key data should be collected on the appropriate page. If this is already in the predefined list above please choose the appropriate value. Please review and update as necessary.

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Header Text: c4591001

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Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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				(b) (4)
Oct-06-2020 15:04:32 (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> Dehydration	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-06-2020 15:04:32 (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
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 01:11:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 3: Closed	Response satisfies query
Oct-20-2020 14:53:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Oct-20-2020 14:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE Urinary tract infection: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-20-2020 14:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Oct-20-2020 14:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RECOVERED/RES OLVED	New Information
Oct-16-2020 05:58:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 3: Opened	SAE RECON:AER#2020387703,outcome was updated to RECOVERED/RESOLVED in Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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				required, please submit a follow-up form.
Oct-13-2020 15:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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

Date	Location	User	Value	Reason
Oct-13-2020 15:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: RECOVERING/ RESOLVING	New Information
Oct-13-2020 15:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Urinary tract infection: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-09-2020 15:33:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Oct-09-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answer ed	Data confirmed, resolved on 10/5/2020. SAE was updated and faxed today 10/9/2020/, pending admission records to confirm medical reason subject was admitted
Oct-09-2020 06:45:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissue d:Opened	SAE RECON 1: Per latest SAE listing,the outcome is still unknown.Please confirm if a follow up AEM form was sent for AER 2020387703.
Oct-08-2020 06:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissue d:Candidate	Pending SDB update
Oct-07-2020 13:32:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answer ed	An updated SAE folow up report was sent.

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Subject Initials: ---

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Oct-07-2020 05:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020387703,outcome was reported as UNKNOWN to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-06-2020 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: RECOVERED/R ESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 15:04:32 (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
Oct-13-2020 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: 2020387703	Initial Entry
Oct-13-2020 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry:	New Information
Oct-07-2020 05:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: 2020387703	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (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
Oct-13-2020 15:53:04 (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
Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Syncope	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/5/2020 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO End Date Time: Oct/5/2020 10:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

Generated By: (b) (4)

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Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 3	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
Oct-23-2020 08:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Oct-22-2020 13:36:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 3: Closed	Response satisfies query
Oct-22-2020 07:26:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Syncope: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-22-2020 07:26:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Oct-22-2020 07:26:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Changed Information
Oct-21-2020 01:13:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 3: Reissued:Open ed	SAE RECON 1:If event confirmed not serious.The answer to the question 'Is the adverse event serious?' should be updated to NO. Please confirm and update as appropriate.

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Header Text: c4591001

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Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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Oct-20-2020 14:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 3: Answered	Please let us to downgrade the event
Oct-16-2020 06:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 3: Opened	SAE RECON:AER#2020387703, SYNCOPE EPISODE was invalidated in Safety database but retained as Serious in AE CRF.Please confirm seriousness. If this event is not serious, please confirm if event should be downgraded on AE CRF.
Oct-13-2020 16:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 15:53:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-13-2020 15:53:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Is this serious event ass ociated with congenital anomaly or birth defect? NO Did this serious event re sult in death? NO Did this serious event re quire or prolong hospita lization? YES Did this serious event re sult in persistent or signi	Transcription Error

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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			<p>ficant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Oct-13-2020 15:53:04 (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.
Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Syncope: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p>	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

			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.

Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (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
Oct-13-2020 15:53:04 (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> Urinary tract Infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (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
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090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 15:53:04 (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
Oct-23-2020 08:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry:	downgraded to non seroius
Oct-13-2020 16:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: 2020387703	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-22-2021 14:00:33 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/15/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-22-2021 14:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per local/national re commendations and confirm ed to have received only pla cebo at Vaccination 1/2	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-22-2021 14:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/15/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-22-2021 14:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-22-2021 14:01:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/22/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-22-2021 14:01:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/22/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-22-2021 14:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/22/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-22-2021 14:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-22-2021 14:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1133**Site Name:** (1133) QPS-MRA, LLC**Subject No:** 11331006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-22-2021 14:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-22-2021 14:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-22-2021 15:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 14:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-22-2021 14:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Jan/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-22-2021 15:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR4ZMJ	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BR4ZMJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-22-2021 15:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BSFD64	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BSFD64	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-22-2021 15:45:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BSFD65	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 15:45:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BSFD65	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 22-Apr-2020 21:03**Site No:** 1133**Subject No:** 11331006**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-22-2021 14:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-22-2021 14:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-22-2021 16:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 14:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-22-2021 14:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Jan/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-22-2021 16:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BR4ZM7	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 16:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BR4ZM7	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (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
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/22/2021 10:30	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: RIGHT	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)	(b) (4)
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7. Route:

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 14:02:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 11:42:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Feb/12/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Data Origin

Date	Location	User	Value	Reason
Feb-12-2021 11:42:12 (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-12-2021 11:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-12-2021 15:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 11:42:12 (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-12-2021 11:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Feb/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-12-2021 15:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BRKJ99	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

5.a Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 15:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BRKJ99	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-12-2021 11:42:38 (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
Feb-12-2021 11:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-12-2021 11:42:38 (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
Feb-12-2021 11:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Feb/12/2021 09:47	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-12-2021 11:42:38 (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
Feb-12-2021 11:42:38 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1133

Subject No: 11331006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:34

Time (US & Canada)		(b) (4)	
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7. Route:

Date	Location	User	Value	Reason
Feb-12-2021 11:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-12-2021 11:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-12-2021 11:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-12-2021 11:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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1. Subject Status

Date	Location	User	Value	Reason
Sep-21-2020 13:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jul-31-2020 11:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jul-31-2020 11:38:54 (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
Oct-07-2020 09:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/5/2020	New Information
Sep-21-2020 13:28:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	Initial Entry
Jul-31-2020 11:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/31/2020	Initial Entry
Jul-31-2020 11:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/30/2020	Initial Entry

090177e196ae3ef7\Final\Final On: 01-Apr-2021 05:05 (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, Signed, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-01-2020 14:48:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry