

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: 11331317

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/28/2020
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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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11331317]
2.	Birth Date:	(b) (6) 1975
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_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: 11331317

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	Aug/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1133

Subject No: 11331317

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331317

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	Aug/28/2020
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: 11331317

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:	[NEARSIGHTED]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[MYOPIA]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[RIGHT INGUINAL HERNIA]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[SURGERY - RIGHT INGUINAL HERNIA REPAIR]
	Start Date:	Jan/UNK/2016
	Ongoing:	NO End Date: Jan/UNK/2016
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[SURGERY - VASECTOMY]
	Start Date:	Dec/UNK/2013
	Ongoing:	NO End Date: Dec/UNK/2013

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/28/2020
2.	Weight:	[75.0]
3.	Unit:	kg
4.	Height:	[172.0]
5.	Unit:	cm
6.	Body Mass Index:	[25.4]

Vital Signs Details

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

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331317

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 :	Aug/28/2020
2.	Randomization Number:	[70859]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8BWS]
5.b	Sample ID	[BP8BWT]
5.c	Sample ID	[BP8BWV]
5.d	Sample ID	[BPFSLF]
5.e	Sample ID	[BPFSLG]

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8BW7]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331317

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/28/2020 13:01
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1133

Subject No: 11331317

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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	Sep/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/23/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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: Sep/23/2020
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	[BP8Y4P]
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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:	Sep/23/2020 12:13
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317 **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/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 11331317 **Subject Initials:** ---

Generated By: (b) (4) **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: Oct/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9CR0]
5.b	Sample ID	[BS82F6]
5.c	Sample ID	[BS82F7]

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331317

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: V4_MONTH6_L

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: 11331317

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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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331317

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331317

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331317

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: V6_MONTH24_L

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: 11331317

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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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

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 Version: 20-Feb-2021 02:17

Site No: 1133

Subject No: 11331317

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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:	[]
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331317

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

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: 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: 11331317

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:	[]
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Health Care Utilization

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

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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: 11331317

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:** 11331317**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 **Form:** DATE OF VISIT
Visit

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

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

Subject No: 11331317 **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: 11331317 **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: 11331317

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/28/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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

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

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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

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: 11331317 **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: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331317

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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

Adverse Event Report

1.	Category:	
2.	AE ID:	[]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

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: 11331317

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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Medication Error

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

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

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: 11331317

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

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

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: 11331317

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:	//

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

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

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

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: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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?	

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

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: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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: 11331317

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:	

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: 11331317

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?	

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

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: 11331317

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

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

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

Subject No: 11331317 **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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

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

Subject No: 11331317 **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: V201_SURVEIL_CONSENT -
Unscheduled

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: 11331317

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

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

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

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

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

Subject No: 11331317 **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	Dec/17/2020
2.	Erroneous Visit	

Header Text: c4591001

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

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

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

Subject No: 11331317 **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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: 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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

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: 11331317

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: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/28/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Aug-28-2020 14:34:44 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-12-2021 14:26:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Howard Schwartz	Approved	Nov-04-2020 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	--	------	--------

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.

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-28-2020 14:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-28-2020 14:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/28/2020	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1133

Subject No: 11331317

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 14:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11331317	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1975	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 14:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-28-2020 14:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331317

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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1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 14:34:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-28-2020 14:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 14:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 14:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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
Aug-28-2020 14:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: NEARSI GHTED Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEARSIGHTED	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-28-2020 14:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His MYOPI tory Term: A Start Date: UNK/U NK/2000 Ongoing: YES	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MYOPIA	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:35:37	ACV0PFEINFP6000	(b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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

(b) (4)

I.c

Date	Location	User	Value	Reason
Aug-28-2020 14:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 3 H Numb er: Medical RIGHT ING History UINAL HE Term: RNIA Start Da UNK/UNK/ te: 2016 Ongoing NO : End Date: UNK/UN K/2016	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT INGUINAL HERNIA	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:38:36	ACV0PFEINFP6000	(b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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

(b) (4)

End Date:

UNK/UNK/2016

1.d

Date	Location	User	Value	Reason
Aug-28-2020 14:40:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/ 4 MH N umber : Medic SURGERY - R al Hist IGH T INGUIN ory Te AL HERNIA rm: REPAIR Start Jan/UNK/2016 Date: Ongoi NO ng: End Date: Jan/UNK/2 016	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:40:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:40:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SURGERY - RIGHT INGUINAL HERNIA REPAIR	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:40:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2016	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:40:10	ACV0PFEINFP6000	(b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)	(b) (4)	End Date: Jan/UNK/2016
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I.e

Date	Location	User	Value	Reason
Aug-28-2020 14:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 5 H Numb er: Medical SURGERY History - VASECTO Term: MY Start Da Dec/UNK/2 te: 013 Ongoing NO : End Date: Dec/UN K/2013	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SURGERY - VASEC TOMY	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/UNK/2013	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 14:40:45	ACV0PFEINFP6000	(b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	End Date: Dec/UNK/2013	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 75.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 172.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 14:42:15 (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
Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.4	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 98.2	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

			Temperature Unit: Temperature Location: ORAL CAVITY : Y	
--	--	--	--	--

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-28-2020 14:42:15 (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
Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 14:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331317

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
Aug-28-2020 14:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 14:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 70859	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331317

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 14:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 14:42:58 (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-28-2020 16:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 14:42:58 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 14:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 16:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP8BW : S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8BWS	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP8BW : T	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8BWT	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 16:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP8BW : V	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8BWV	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

5.d

Date	Location	User	Value	Reason
Aug-28-2020 17:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPFSLF	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 17:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPFSLF	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPFSL : G	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPFSLG	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

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-28-2020 14:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 14:43:05 (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
Aug-28-2020 16:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 14:43:05 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 14:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 16:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP8BW : 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8BW7	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331317

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-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020 13:01	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 14:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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-28-2020 14:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 01:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Oct-14-2020 16:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	A protocol deviation was performed. Subject came out of window due to work.
Sep-24-2020 06:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (3 day) from DOV (28/Aug /2020) at VID1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331317

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

				details as appropriate.
Sep-23-2020 13:38:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sep/23/2020	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Sep-23-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: Temperature Free Unit: Temperature Oral Location: Notes: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 13:45:00 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-23-2020 13:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

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
Sep-23-2020 13:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 13:45:13 (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
Sep-24-2020 10:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-24-2020 05:37:31 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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:** 11331317**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 13:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 13:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 10:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP8Y4 D: P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Sep-24-2020 10:26:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8Y4P	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331317

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
Sep-23-2020 13:46:34 (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
Sep-23-2020 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-23-2020 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020 12:13	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-23-2020 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-28-2020 13:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317 **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-28-2020 13:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-28-2020 13:21:25 (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-29-2020 08:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-29-2020 07:28:47 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 13:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 13:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-29-2020 08:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR9CR : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 11331317 Subject Initials: ---

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

Oct-29-2020 08:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR9CR0	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-29-2020 09:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS82F6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 09:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS82F6	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-29-2020 09:27:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BS82F D: 7	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 09:27:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS82F7	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: 11331317

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
Nov-02-2020 16:31:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-02-2020 14:45:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Data has been corrected
Nov-02-2020 14:45:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020	Data has been corrected
Nov-02-2020 12:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

Subject No: 11331317 **Subject Initials:** ---

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

				2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match the date the Visit 3.
Sep-23-2020 13:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-23-2020 13:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-23-2020 13:49:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				
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Header Text: c4591001

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

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

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

Subject No: 11331317 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 14:27:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

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

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

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

Subject No: 11331317 **Subject Initials:** ---

Generated By: (b) (4) **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
Feb-12-2021 14:27:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-12-2021 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-12-2021 14:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

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: 11331317

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-23-2020 13:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-28-2020 14:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 14:34:59 (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
Nov-02-2020 14:45:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/28/2020	Data has been corrected
Sep-23-2020 13:49:49	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (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: 11331317

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)				
Aug-28-2020 14:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry
Aug-28-2020 14:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331317

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 08:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3ef3\Final\Final On: 01-Apr-2021 05:04 (GMT)