

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION

**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](#)

**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:** 11331207

**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/19/2020
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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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11331207]
2.	Birth Date:	(b) (6)/1999
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/19/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1133

**Subject No:** 11331207

**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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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**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/19/2020
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:** 11331207

**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

[Form Comments](#)

**Medical History Details**

1.	Line/MH Number:	Not Applicable _____ [ ]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ [ ]
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/19/2020
2.	Weight:	[68.9]
3.	Unit:	kg
4.	Height:	[159.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/19/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**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/19/2020
2.	Randomization Number:	[56917]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY1RD]
5.b	Sample ID	[BPY1RF]
5.c	Sample ID	[BPY1RG]
5.d	Sample ID	[BPFSD9]
5.e	Sample ID	[BPFSD8]

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY1PK]
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090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1133

**Subject No:** 11331207

**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/19/2020 16:52
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

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1133

**Subject No:** 11331207

**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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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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

Date of Visit			
1.	Date of Visit	Not Applicable _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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

**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	Temperature:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Unit:	Not Applicable _____	<a href="#">Comments</a>
	Temperature Location:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 30-Jul-2020 21:27

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ [ ]
----	-----------	--------------------------------

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331207

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

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	Not Applicable _____	<a href="#">Comments</a>
2.	Treatment Name	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Applicable _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Applicable _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Applicable _____	<a href="#">Comments</a>
6.	Body Side:	Not Applicable _____	<a href="#">Comments</a>
7.	Route:	Not Applicable _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Applicable _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Applicable _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Applicable _____	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**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:** V3\_MONTH1\_POSTVAX2\_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:** 11331207

**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:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**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 Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**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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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**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:** 11331207

**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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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**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 Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**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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**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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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:** 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:** 11331207

**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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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:** 11331207

**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:	
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**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:** 11331207

**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:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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:** 11331207

**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:** 11331207

**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 :	Sep/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[SUBJECT WITHDREW CONSENT]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Sep/30/2020	<a href="#">Comments</a>
2.	Phase of Disposition:	FOLLOW-UP	<a href="#">Comments</a>
3.	Status:	WITHDRAWAL BY SUBJECT	<a href="#">Comments</a>
4.	Specify Status:	[Subject withdrew consent]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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:** 11331207

**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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090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	Exposure During Pregnancy	Aug/19/2020 16:52	NO End Date Time: Sep/26/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure During Pregnancy]	
4.	Start Date Time:	Aug/19/2020 16:52	
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/26/2020 UNK:UNK	
6.	Toxicity Grade:	Not Applicable	<a href="#">Comments</a>
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Pregnacy]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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

**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:** 11331207

**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.						<a href="#">Repeating Pages</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[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	[ ]

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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:** 11331207

**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.						<a href="#">Repeating Pages</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Status:** Not Started

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

**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.	Date:	//

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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.						<a href="#">Repeating Pages</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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.						<a href="#">Repeating Pages</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

**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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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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:** 11331207

**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:** 11331207

**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:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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?	

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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:** 11331207

**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 - 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:** 11331207 **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:** 11331207

**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 - Unscheduled    **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:** 11331207

**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:** 11331207

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

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Not Applicable	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Not Applicable _____ //	<a href="#">Comments</a>
2.	Primary Reason for Unblinding:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	Sep/30/2020
----	------------------------------	-------------

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	<a href="#">Comments</a>
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**Cause of Death**

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ [ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/30/2020

**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:** 11331207

**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
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090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**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:** 11331207

**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 Version:** 30-Jul-2020 21:29

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**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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Item	Date	User	Comment
Form	Aug-19-2020 17:32:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - Comments

**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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Item	Date	User	Comment
Form	Aug-19-2020 17:34:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - Comments

**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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Item	Date	User	Comment
Form	Oct-29-2020 10:31:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject is not expected for visit 2. Subject withdrew consent
			Not Applicable

**Header Text:** c4591001

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**Form Version:** 22-Apr-2020 21:02

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**Subject No:** 11331207

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

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**Subject Initials:** ---

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

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Item	Date	User	Comment
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**Subject Initials:** ---

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

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**Form Version:** 10-Oct-2020 16:01

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - Comments

**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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Item	Date	User	Comment
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Form	Oct-29-2020 10:31:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent

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

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Item	Date	User	Comment
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**Subject Initials:** ---

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Item	Date	User	Comment
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**Subject Initials:** ---

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Item	Date	User	Comment
2.a	Oct-29-2020 10:31:52 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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**Form Version:** 30-Jul-2020 21:27

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**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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Item	Date	User	Comment
Form	Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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Item	Date	User	Comment
1	Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Site Name:** (1133) QPS-MRA, LLC

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

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Item	Date	User	Comment
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**Header Text:** c4591001

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**Form Version:** 30-Jul-2020 21:27

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

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Item	Date	User	Comment
6.a	Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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**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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Item	Date	User	Comment
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**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

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Item	Date	User	Comment
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**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

**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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Item	Date	User	Comment
Form	Oct-29-2020 10:32:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

**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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Item	Date	User	Comment
1	Oct-29-2020 10:32:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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**Site Name:** (1133) QPS-MRA, LLC

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

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Item	Date	User	Comment
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Item	Date	User	Comment
3	Oct-29-2020 10:32:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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**Subject Initials:** ---

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Item	Date	User	Comment
4	Oct-29-2020 10:32:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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**Subject No:** 11331207

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**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Form Status:** Data Complete, Locked, Frozen, Verified

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**Subject Initials:** ---

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

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
11	Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent
			Not Applicable

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent Not Applicable

**Header Text:** c4591001

**Visit:** Follow-Up

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent Not Applicable

**Header Text:** c4591001

**Visit:** Follow-Up

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent Not Applicable

**Header Text:** c4591001

**Visit:** Follow-Up

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent Not Applicable

**Header Text:** c4591001

**Visit:** Follow-Up

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject withdrew consent Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
6	Nov-16-2020 14:18:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Mar-03-2021 15:41:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact

**Form:** DATE OF VISIT - Comments

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
1	Mar-03-2021 15:41:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Feb-24-2021 12:17:15 (UTC-05:00) Eastern Time (US & Canada)	Karla Pentzke (b) (4)	withdrew consent Not Done
1	Feb-23-2021 12:41:27 (UTC-05:00) Eastern Time (US & Canada)	Karla Pentzke (b) (4)	withdrew consent Not Applicable

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact

**Form:** DATE OF VISIT - Comments

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
2	Mar-03-2021 15:41:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Mar-03-2021 15:30:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Mar-03-2021 15:30:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Oct-29-2020 10:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Oct-29-2020 10:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Oct-29-2020 10:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Oct-29-2020 10:33:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Oct-29-2020 10:33:42 (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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Nov-30-2020 11:47:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Howard Schwartz	Approved	Nov-17-2020 11:38:02 (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.

(b) (6)	N/A	Nov-16-2020 12:49:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Howard Schwartz	Approved	Nov-15-2020 18:26:20 (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.

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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:** 11331207

**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-19-2020 17:31:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 17:31:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-19-2020 17:31:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-20-2020 10:41:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-18-2020 14:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The A/E was created
Sep-18-2020 06:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER# 2020326673 PREGNANCY (onset date 20AUG2020) was reported to Pfizer Safety but missing in AE CRF. Per protocol All AEs/SAEs associated with exposure during pregnancy or breastfeeding should be reported in AE CRF. Please confirm.
Aug-19-2020 17:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11331207	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-19-2020 17:31:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1999	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-19-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Aug-19-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRICAN AMERICAN	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-19-2020 17:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/19/2020	Initial Entry

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: 11331207

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
Aug-19-2020 17:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-19-2020 17:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-19-2020 17:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/19/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 68.9	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 159.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 27.3	Initial Entry

**7.a**

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.9 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY <b>n::</b> Y	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.9	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1133**Subject No:** 11331207**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/19/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Result:</b> NEGATIVE	
			<b>Not Done:</b>	

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-18-2020 13:33:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Sep-18-2020 12:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	An Adverse Event form was created
Sep-16-2020 10:43:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	11331207: Clinical_Subject had a positive pregnancy test after Vax 1. Per CRF CG 8.46.2.5. Pregnancy is to be reported as an AE. Please update the AE log accordingly.
Aug-19-2020 17:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**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-19-2020 17:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/19/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 56917	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

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-19-2020 17:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-20-2020 16:57:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-20-2020 05:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 17:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 17:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-20-2020 16:57:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Sample ID: BPY1RD	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:57:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BPY1RD	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-20-2020 16:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BPY1RF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BPY1RF	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-20-2020 16:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BPY1RG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 16:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> BPY1RG	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-20-2020 17:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u>Data Entry:</u> Sample ID: BPFSD9	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

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

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-20-2020 17:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> BPFSD9	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-20-2020 17:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BPFSD9	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-20-2020 17:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> BPFSD9	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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: 11331207

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-19-2020 17:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-20-2020 16:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-20-2020 05:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 17:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 17:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-20-2020 16:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Sample ID: BPY1PK	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-20-2020 16:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<u><b>Data Entry:</b></u> BPY1PK	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331207

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-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/19/2020 16:52	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 17:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-19-2020 17:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) )	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-29-2020 10:31:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-02-2020 01:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 11:55:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject withdrew consent as of 30/SEP/20. No visit will be performed.
Sep-25-2020 11:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Oct-29-2020 10:31:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

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
Oct-29-2020 10:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-29-2020 10:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> Not Applicable <b>Temperature Unit:</b> Not Applicable <b>Temperature Location::</b> Not Applicable	Initial Entry
Oct-29-2020 10:31:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Location::</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-29-2020 10:31:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-29-2020 10:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-29-2020 10:31:52	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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**2.a Temperature Location:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-29-2020 10:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Result:</b>	Not Applicable
			<b>Not Done:</b>	Not Applicable

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

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-29-2020 10:32:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1133

Subject No: 11331207

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
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-09-2020 16:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Disp EOT and FUP completed - confirmed subj withdrew and V2 will not occur
Nov-09-2020 16:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5325530;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

Canada)			ble	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1133

**Subject No:** 11331207

**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

Oct-29-2020 10:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-01-2020 11:58:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-01-2020 11:58:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-04-2020 18:21:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	per site response
Nov-04-2020 08:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data is correct. Subject withdrew consent. Not related to pregnancy
Nov-04-2020 07:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: EOT is reported due to Withdrawal by Subject on 30Sep20. Subject had pregnancy reported prior to this date. Please review and confirm that reason for end of treatment was withdrawal of consent not related to the pregnancy
Oct-01-2020 11:58:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WITHDRAWAL BY SUBJECT	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
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090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Oct-01-2020 11:58:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SUBJECT WITHDREW CONSENT	Initial Entry
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090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-09-2020 16:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 11:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-09-2020 11:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry
Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-06-2020 14:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Will the subject stay in the study for follow-up? If not, please enter the date and status of discontinuation in DISP FUP form.
Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-09-2020 11:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Status:**

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**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Date	Location	User	Value	Reason
Nov-09-2020 11:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WITHDRAWAL BY SUBJECT	Initial Entry
Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Nov-09-2020 11:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject withdrew consent	Initial Entry
Nov-09-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-29-2020 10:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-17-2020 05:11:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	term updated in SDB to maternal exposure during pregnancy
Nov-16-2020 11:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Pending SDB update
Nov-16-2020 09:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	SAE Form was updated and faxed on Friday 11/13/2020.
Nov-10-2020 07:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 2: Thank you for updating AE CRF. Please confirm if a follow up AEM form was submitted to also update the term in Safety database to Exposure during pregnancy.
Nov-10-2020 07:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	As per query
Nov-10-2020 07:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exposure During Pregnancy	As per query
Nov-07-2020 11:31:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1:Per latest update in 8.50.2.5 Specific Guidance for Pregnancy, a

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1133**Subject No:** 11331207**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

				healthy Pregnancy is not an AE that is required to be on the CRF. "Exposure During Pregnancy" will be recorded as an AE log instead. Please update accordingly.
Nov-05-2020 23:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON: For Clinical review
Nov-05-2020 11:58:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EDP was updated after the pregnancy not prior, therefore, medical term should not be updated.
Nov-03-2020 08:48:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020326673, the term in both database was recorded as pregnancy. Based on the latest EDP guidance,the term should be reported as 'EXPOSURE DURING PREGNANCY'. Please confirm and update.A follow up AEM form is required to update SDB.
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pregnacy	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-02-2020 09:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Onset date updated in SDB to 19Aug2020
Dec-01-2020 06:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON: Thank you for the update. However, the onset date was still recorded as 20Aug2020 in Safety database. A follow up AEM form is required to update onset date in SDB, please submit a follow up form.
Nov-30-2020 11:47:01 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1133**Subject No:** 11331207**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

Time (US & Canada)				
Nov-30-2020 11:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b)(6)	<b>Data Entry:</b> Aug/19/2020 16:52	Changed Information
Nov-25-2020 05:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020326673, per narrative "The first day of LMP was on 19Jul2020". Per CRF CV v10_ section 8.50.2.5 Specific Guidance for Pregnancy, when the participant was pregnant before enrollment,the onset date=date of Vax1(19Aug2020).Please update
Sep-22-2020 06:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	onset date updated in SDB
Sep-20-2020 10:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020345020
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 16:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-07-2020 14:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/26/2020 UNK:UNK	Transcription Error
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/16/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-16-2020 16:44:53 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	Query 1: Closed	Response satisfies query

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1133**Subject No:** 11331207**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1133) QPS-MRA, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

(US & Canada)		(b) (4), (b) (6)		
Nov-16-2020 14:19:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Answered	Data updated
Nov-16-2020 14:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 13:33:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Reissued:Opened	Please add Item level comment of Not Applicable. Please refer to CRF Completion Requirements section 4.10.
Nov-16-2020 12:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-16-2020 12:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-15-2020 01:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Toxicity grade is not expected for pregnancy related adverse events, hence please remove the toxicity and add item level comment as NOT APPLICABLE.
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Oct-03-2020 09:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

Oct-02-2020 17:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Response satisfies query
Oct-02-2020 15:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Pregnancy: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-02-2020 15:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-02-2020 15:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Sep-29-2020 09:44:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	The pregnancy was appropriately reported to safety; however, seriousness criteria is met only if there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Sep-20-2020 10:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-18-2020 12:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-18-2020 12:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO	Transcription Error

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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			<p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p>	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Subject Initials: ---

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			NO	
			Did this serious event require or prolong hospitalization?	
			NO	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Pregnancy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-03-2020 09:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	To confirm with PSSR if acceptable discrepancy per case processing convention
Sep-23-2020 05:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020326673,outcome was reported as UNKNOWN in SAE form however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1133) QPS-MRA, LLC

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-22-2020 11:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	GPDClin: Closed this query as it was raised based on a wrong SAE case number. The correct SAE case number for this case is 2020326673.
Sep-20-2020 10:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020345020,outcome was reported as UNKNOWN in SAE form however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 12:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-03-2020 09:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	downgraded to No in Inform and not serious in SDB but valid case.. As per Safety when no adverse is reported in an Exposure During Pregnancy case report, the Case seriousness is captured as Non-Serious. The case is retained as a valid case report in SDB
Sep-22-2020 07:05:56	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	AER corrected

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

(UTC-05:00) Eastern Time (US & Canada)		(b)(4), (b)(6)	2020326673	
Sep-20-2020 10:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020345020	Initial Entry

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1133

Site Name: (1133) QPS-MRA, LLC

Subject No: 11331207

Subject Initials: ---

Generated By: (b) (4)

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-04-2021 09:01:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-03-2021 15:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-24-2021 20:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Reissued :Opened	DM: If REVAX CONT was not done, please consider removing all data from corresponding forms, e.g., from REVAX CONF and mark forms with 'Not Applicable' using a form-level comment.
Feb-24-2021 12:17:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	Query 1: Answered	Changed data per query
Feb-24-2021 12:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-24-2021 07:31:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7403156;FURTHER VACCINATION CONFIRMATION CRF is completed, however date of visit is missing for REVAX_CONTACT. Please review and update as appropriate.

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

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

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Feb-23-2021 12:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**2. Erroneous Visit**

Date	Location	User	Value	Reason
Mar-03-2021 15:41:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**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
Mar-03-2021 15:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-03-2021 15:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-23-2021 12:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Karla Pentzke (b) (4)	<b>Data Entry:</b> Participant is NOT willing to return f or Vaccination 3 OR otherwise not el igible	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Oct-29-2020 10:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Oct-29-2020 10:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1133

**Subject No:** 11331207

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1133) QPS-MRA, LLC

**Subject Initials:** ---

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

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***1. Withdrawal of Consent Date :***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-12-2020 07:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 11:21:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 20:05:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: If subject is completely withdrawn from the study, please complete the Disposition Follow up CRF. Refer to CCR section 8.56 for information/guidance.
Oct-01-2020 11:55:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED - 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:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-29-2020 10:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1133

Subject No: 11331207

Generated By: (b) (4)

Form: SUBJECT STATUS - 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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**I. Subject Status**

Date	Location	User	Value	Reason
Nov-09-2020 11:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-01-2020 11:58:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Aug-19-2020 17:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 17:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-09-2020 11:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/30/2020	Initial Entry
Oct-01-2020 11:58:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/30/2020	Initial Entry
Aug-19-2020 17:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/19/2020	Initial Entry
Aug-19-2020 17:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/19/2020	Initial Entry

090177e196ae3ef6\Final\Final On: 01-Apr-2021 05:05 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Verified

**Site No:** 1133

**Site Name:** (1133) QPS-MRA, LLC

**Subject No:** 11331207

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-22-2020 07:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry