

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** COHORT SELECTION

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/7/2020
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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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10791076]
2.	Birth Date:	(b) (6)/1961
3.	Sex:	FEMALE
4.	Ethnicity:	NOT 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:** 1079

**Subject No:** 10791076

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

**Form:** DATE OF VISIT

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/7/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/7/2020
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:** 1079

**Subject No:** 10791076

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type II Diabetes]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hot Flashes]
	Start Date:	Jul/UNK/2020
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Blind (R - Eye)]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post-Menopausal]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/7/2020
2.	Weight:	[211.2]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[36.2]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD

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**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[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>

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**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** RANDOMIZATION

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/7/2020
2.	Randomization Number:	[223894]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/7/2020
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	[BMPYHD]
5.b	Sample ID	[BMPYHF]
5.c	Sample ID	[BNBCJP]
5.d	Sample ID	[BNBCJR]
5.e	Sample ID	[BNBCJS]

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/7/2020
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	[BNBCJ5]
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090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** VACCINATION

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[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/7/2020 10:48
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

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** DATE OF VISIT

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/28/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/28/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	FOREHEAD

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[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>

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPXVMF]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** VACCINATION

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/28/2020 09:27
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

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/29/2020
2.	Erroneous Visit	



**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	
3.	Injection Site Location:	DELTOID MUSCLE	
4.	Injection Site Body Side:	LEFT	<a href="#">Comments</a>
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	NO	

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1079**Site Name:** (1079) PMG Research of Charlotte LLC**Subject No:** 10791076**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPB0P7]
5.b	Sample ID	[BLG0S6]
5.c	Sample ID	[BLG0RP]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** DATE OF VISIT

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/19/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BS236D]
5.b	Sample ID	[BRN1GR]
5.c	Sample ID	[BS236N]

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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	[ ]
----	-----------	-----

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

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

**Site No:** 1079

**Subject No:** 10791076

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

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

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**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	[ ]
----	-----------	-----

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

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

**Site No:** 1079

**Subject No:** 10791076

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

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

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**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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090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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?	
----	--	--

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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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090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Unplanned Assessments**

1.	Assessments	
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**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Sep/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - **Form:** DATE OF VISIT - REPEAT SWAB  
New Unscheduled Visit

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Uterine Cancer	Jan/25/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791076

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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[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)	[Uterine Cancer]
4.	Start Date Time:	Jan/25/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event NO

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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: [Unopposed ERT]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021187485]

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Category	Medication Error	Start Date	Is the medication error S till Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Medication Error**

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

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Concomitant Medications**

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

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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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?	

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[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?	

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:	



**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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?	

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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	[ ]
----	-----------	-----

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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	[ ]
----	-----------	-----

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/19/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/19/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/29/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
George Raad	Approved	Mar-10-2021 18:41:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, GeorgeRaad, 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.

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

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

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-07-2020 16:34:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable



**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
3	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
4	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
5	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable



**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
1	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
3	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
4	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
5	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
6.a	Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
4	Oct-23-2020 09:18:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
4	Sep-29-2020 16:19:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	NA <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
George Raad	Approved	Mar-10-2021 18:41:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, GeorgeRaad, 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	Feb-22-2021 18:04:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

George Raad	Approved	Jan-22-2021 10:13:50 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-21-2021 16:49:06 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

George Raad	Approved	Oct-27-2020 13:06:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Oct-23-2020 09:18:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

George Raad	Approved	Oct-12-2020 11:17:41 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Sep-29-2020 16:18:18 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

George Raad	Approved	Sep-16-2020 14:54:14 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, GeorgeRaad, 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.

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-07-2020 14:05:55 (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-07-2020 14:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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***1. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-07-2020 14:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent O btained  Aug/7/2020	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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-07-2020 14:05:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10791076	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-07-2020 14:05:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1961	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-07-2020 14:06:29 (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
Aug-07-2020 14:06:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LAT INO(A) OR OF SPANIS H ORIGIN	Initial Entry

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

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

Date	Location	User	Value	Reason
Aug-07-2020 14:06:29 (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:** 1079

**Subject No:** 10791076

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

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

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-07-2020 14:13:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Aug-07-2020 14:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-07-2020 14:13:55 (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-07-2020 14:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1.a**

Date	Location	User	Value	Reason
Aug-07-2020 14:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 1 mber: Medical Hist Hyperchole ory Term: sterolemia Start Date: UNK/UNK/ 2019 Ongoing: YES	Initial Entry

**1.a Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 14:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 14:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypercholesterolemia	Initial Entry

**1.a Start Date:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Aug-07-2020 14:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry
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***1.a Ongoing:***

Date	Location	User	Value	Reason
Aug-07-2020 14:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Aug-07-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 2 <b>Medical History Term:</b> Type II Diabetes <b>Start Date:</b> UNK/UNK/1989 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type II Diabetes	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1989	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 14:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

*I.c*

Date	Location	User	Value	Reason
Aug-07-2020 14:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Depression <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 14:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-07-2020 14:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Depression	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 14:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 14:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

*I.d*

Date	Location	User	Value	Reason
Aug-07-2020 14:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 4 <b>mber:</b> <b>Medical Histo</b> GERD <b>ry Term:</b> <b>Start Date:</b> UNK/UN K/2015 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 14:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 14:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> GERD	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 14:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 14:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

*I.e*

Date	Location	User	Value	Reason
Aug-07-2020 14:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 5 <b>mber:</b> <b>Medical Histo</b> Hypertens <b>ry Term:</b> ion <b>Start Date:</b> UNK/UN K/2015 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Aug-07-2020 14:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 14:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

***I.e Start Date:***

Date	Location	User	Value	Reason
Aug-07-2020 14:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Aug-07-2020 14:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

*I.f*

Date	Location	User	Value	Reason
Aug-07-2020 14:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 6 <b>ber:</b> <b>Medical History Term:</b> Hot Flashes <b>Start Date:</b> Jul/UNK/ 2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

***1.f Line/MH Number:***

Date	Location	User	Value	Reason
Aug-07-2020 14:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

***1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-07-2020 14:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hot Flahses	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Aug-07-2020 14:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/UNK/2020	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
Aug-07-2020 14:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

*I.g*

Date	Location	User	Value	Reason
Aug-07-2020 14:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 7 <b>mber:</b> <b>Medical Histo</b> Blind (R - <b>ry Term:</b> Eye) <b>Start Date:</b> UNK/UN K/2014 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Aug-07-2020 14:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

***1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-07-2020 14:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blind (R - Eye)	Initial Entry

***1.g Start Date:***

Date	Location	User	Value	Reason
Aug-07-2020 14:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Aug-07-2020 14:18:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

*I.h*

Date	Location	User	Value	Reason
Aug-07-2020 14:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 8 <b>mber:</b> <b>Medical Histo</b> Post-Meno <b>ry Term:</b> pausal <b>Start Date:</b> UNK/UN K/2005 <b>Ongoing:</b> YES	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

**1.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 14:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-07-2020 14:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Post-Menopausal	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 14:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 14:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Date:**

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 211.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 64.0	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Eastern Time (US & Canada)

5. Unit:

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 36.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature</b> 97.6 <b>:</b> <b>Temperature</b> F <b>Unit:</b> <b>Temperature</b> FORE <b>Location::</b> HEAD	Initial Entry

7.a Record Identifier:

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (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-07-2020 14:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-07-2020 14:19:34 (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-07-2020 14:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-07-2020 14:19:50 (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
Aug-07-2020 14:19:50 (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
Aug-07-2020 14:19:50 (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
Aug-07-2020 14:19:50 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

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: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Eastern Time (US  
& Canada)

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-07-2020 14:19:50 (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
Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defi</b> Not Ap <b>ned Identifie</b> plicable <b>r:</b> <b>Test::</b> Not Ap plicable <b>Result::</b> Not Ap plicable <b>Not Done::</b> Not Ap plicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)



**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**6.a Test:**

Date	Location	User	Value	Reason
Aug-07-2020 14:19:50 (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
Aug-07-2020 14:19:50 (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
Aug-07-2020 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-07-2020 14:20:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-07-2020 14:20:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 223894	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-07-2020 14:20:54 (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-07-2020 14:20:54 (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-07-2020 14:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-07-2020 14:20:54 (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.

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Aug-07-2020 14:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/7/2020	Initial Entry
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**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Aug-13-2020 21:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-12-2020 09:12:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-11-2020 06:12:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject is listed to have:2 serum samples, which is less than the 5 expected. Please review and update Q4 as appropriate, else clarify.

**5.a**

Date	Location	User	Value	Reason
Aug-07-2020 14:21:56 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BMPYH : D	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Eastern Time (US & Canada)

5.a Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 14:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMPYHD	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-07-2020 14:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BMPYHF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 14:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMPYHF	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-12-2020 09:12:22	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNBCJP	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 09:12:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNBCJP	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-12-2020 09:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BNBCJR	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 09:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNBCJR	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-12-2020 09:12:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BNBCJS	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

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

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-12-2020 09:12:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNBCJS	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-07-2020 14:22:33 (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-07-2020 14:22:33 (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-07-2020 14:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-07-2020 14:22:33 (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.

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Aug-07-2020 14:22:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/7/2020	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Aug-07-2020 14:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BNBCJ5</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-07-2020 14:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNBCJ5	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-07-2020 14:29:30 (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-07-2020 14:29:30 (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-07-2020 14:29:30 (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-07-2020 14:29:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020 10:48	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791076

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-07-2020 14:29:30 (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-07-2020 14:29:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-07-2020 14:29:30 (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-07-2020 14:29:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIF IED OBSERVATION PERI OD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

Aug-07-2020 14:29:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-07-2020 14:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENI CITY E-DIARY COLL ECTED FOR THIS SU BJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

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

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-31-2020 20:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or sys N <b>temic symptoms</b> O <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or sy N</b> <b>stemic symptoms O</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.b Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or sy</b> NO <b>stemic symptom</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.c Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI L LS  <b>Were fever or sys N</b> <b>temic symptoms O</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.d Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> VO MI TI NG  Were fever or sy NO stemic symptom s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.e Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or sy</b> NO <b>stemic symptom</b> <b>s present on the</b> <b>last day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.f Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> NEW OR W ORSE NED MUSC LE PA IN	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1079**Site Name:** (1079) PMG Research of Charlotte LLC**Subject No:** 10791076**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05

			Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
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**2.g Symptom:**

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED J	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

			OINT PAIN  Were fever or r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed?:	
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2.h Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: RE D NE SS  Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW EL LI NG <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT I NJE CTI ON S ITE <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 20:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Date:**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature 97.4</b> <b>:</b> <b>Temperature F</b> <b>Unit:</b> <b>Temperature FORE</b> <b>Location:: HEAD</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:04 (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
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090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Aug-31-2020 20:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.4	Initial Entry
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**2.a Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:11 (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
Aug-31-2020 20:25:11 (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
Aug-31-2020 20:25:11 (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
Aug-31-2020 20:25:11 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Eastern Time (US  
& Canada)

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-31-2020 20:25:11 (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
Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Def</b> Not Ap <b>ined Identifi</b> plicabl <b>er:</b> e <b>Test::</b> Not Ap plicabl e <b>Result::</b> Not Ap plicabl e <b>Not Done::</b> Not Ap plicabl e	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 20:25:11 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Eastern Time (US  
& Canada)

**6.a Test:**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:11 (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
Aug-31-2020 20:25:11 (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
Aug-31-2020 20:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:32 (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-31-2020 20:25:32 (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-31-2020 20:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 20:25:32 (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.

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Aug-31-2020 20:25:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/28/2020	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BPXVM : F	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 20:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPXVMF	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-31-2020 20:26:19 (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-31-2020 20:26:19 (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-31-2020 20:26:19 (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-31-2020 20:26:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020 09:27	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 20:26:19 (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-31-2020 20:26:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-31-2020 20:26:19 (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-31-2020 20:26:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIF IED OBSERVATION PERI OD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

Aug-31-2020 20:26:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-29-2020 16:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or syst N emic symptoms pr O esent on the last d ay the Subject Dia ry was completed ?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F A T I G U E  <b>Were fever or sys</b> N <b>temic symptoms</b> O <b>present on the las</b> <b>t day the Subject</b> <b>Diary was comple</b> <b>ted?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.b Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.c Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI L LS  <b>Were fever or syst N emic symptoms p O resent on the last day the Subject D iary was complete d?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.d Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.e Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was compl</b> <b>eted?:</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.f Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUSC LE PAI N  <b>Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?:</b> NO	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.g Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED J OINT PAIN  <b>Were fever or systemic symp toms present on the last da y the Subject Diary was co mpleted?:</b> NO	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

2.h Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-23-2020 13:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Oct-23-2020 09:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-23-2020 09:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
Oct-23-2020 09:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-22-2020 19:23:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (b) (4)	Query 1: Opened	V2 vaccination body side is reported as "LEFT" while V3 Injection site body side is reported as "Not Applicable". Please review and update as appropriate.
Sep-29-2020 16:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b>  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	Initial Entry  RE D NE SS N O
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**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW EL	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1079**Site Name:** (1079) PMG Research of Charlotte LLC**Subject No:** 10791076**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05

Eastern Time (US & Canada)			LIN G	
			Were injection site reactions present on the last day the Subject Diary was completed?:	NO

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT I NJEC TION	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

			SITE	
			Were injection site reactions present on the last day the Subject Diary was completed?:	NO

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1079**Site Name:** (1079) PMG Research of Charlotte LLC**Subject No:** 10791076**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-29-2020 16:27:17 (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
Sep-29-2020 16:27:17 (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
Sep-29-2020 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/29/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-29-2020 16:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPB0P7	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 16:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPB0P7	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 16:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BLG0S6</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 16:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLG0S6	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 16:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BLG0RP</b>	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**5.c Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-29-2020 16:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLG0RP	Initial Entry

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1079

**Subject No:** 10791076

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

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

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-22-2021 18:04:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/19/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-22-2021 18:04:56 (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
Feb-22-2021 18:04:56 (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
Feb-22-2021 18:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 18:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Feb-22-2021 18:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/19/2021	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Feb-22-2021 18:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS236D	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-22-2021 18:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS236D	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-22-2021 18:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRN1G : R	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-22-2021 18:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRN1GR	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-22-2021 18:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS236N	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-22-2021 18:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS236N	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Sep-29-2020 16:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-29-2020 16:32:33 (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
Sep-29-2020 16:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Date	Location	User	Value	Reason
Feb-23-2021 15:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Category:**

Date	Location	User	Value	Reason
Feb-23-2021 15:12:43 (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
Feb-23-2021 15:12:43 (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
Mar-08-2021 17:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	no presenting complaint reported; closing for data lock
Mar-04-2021 16:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Including this in the SAE submission today.
Mar-04-2021 12:55:22 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SAE states TAH + BSO on 09Feb2021

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Eastern Time (US & Canada)				
Mar-04-2021 12:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Query closed; will follow for requested uterine CA histopathologic information.
Mar-04-2021 12:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Open	Clinical - due to data lock, please submit Subject's report as to how she came to schedule surgery on Jan 25, 2021
Mar-04-2021 12:50:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 12:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-24-2021 17:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Sent a follow-up SAE
Feb-24-2021 17:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Waiting on Medical Records.

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

& Canada)				
Feb-24-2021 17:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Sent a follow-up SAE
Feb-24-2021 17:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Sent a Follow-up SAE
Feb-24-2021 17:53:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Waiting on Medical records.
Feb-23-2021 18:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical Please submit tumor stage and histopathological results in a SAE safety update
Feb-23-2021 18:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical Please submit a SAE update with the clinical course which led to Uterine CA diagnosis (signs or symptoms, exam, diagnostic imaging, etc)
Feb-23-2021 18:39:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Please submit any

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1079**Site Name:** (1079) PMG Research of Charlotte LLC**Subject No:** 10791076**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		medications taken for systemic conditions (for HTN, T2DM, etc) to the SAE Com Meds section
Feb-23-2021 18:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical SAE report Med Hx section says 'not applicable'; however, for surgical/radiation subject with malignancy, systemic conditions are relevant. Please submit to SAE Med hx (HTN, T2DM, other)
Feb-23-2021 18:35:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical SAE report specifies total Abd Hysterectomy performed on 08Feb21; please submit information to SAE whether bilat oophorectomy was also performed (Yes/No)
Feb-23-2021 15:12:43 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Uterine Cancer	Initial Entry



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Eastern Time (US & Canada)

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-23-2021 15:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 15:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-04-2021 12:47:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 10:20:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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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

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Feb-24-2021 10:20:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Transcription Error
Feb-23-2021 18:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Toxicity/severity grade is 3; however, serious criteria include Life-threatening which is grade 4 (protocol Sect 10.3.3). Please harmonize, updating whichever parameter is required, in both AE/SAE report
Feb-23-2021 15:12:43 (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
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**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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Mar-05-2021 20:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 16:06:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-04-2021 16:06:55 (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 Did this serious event require or prolong hospitalization?  YES Did this serious event result in persistent or significant disability/incapacity?  NO	New Information

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

			<p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Mar-04-2021 12:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query closed; will follow for requested COVID test information.
Mar-04-2021 12:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Clinical thank you; Serious criteria are now HOSP and Life-threatening in SAE; however, only Hosp here on AE log. Please harmonize reporting / update.
Feb-24-2021 17:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Waiting on Medical Records.
Feb-24-2021 17:53:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Submitted Follow-Up SAE

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**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

& Canada)				
Feb-24-2021 03:38:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 18:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021187485] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-23-2021 18:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - serious criteria do not include Hospitalization; however, SAE report states subject was hospitalized from Feb 8-9, 2021 for TAH surgery. Please review, and update serious criteria as

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

				required in both AE/SAE report.
Feb-23-2021 15:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Uterine Cancer: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-23-2021 15:12:43 (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 Did this serious event require or prolong hospitalization?  NO Did this serious event result in persistent or significant disability/incapacity?  NO	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

			Is this serious event life threatening?  YES  Other medically important serious event  NO	
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**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-23-2021 15:12:43 (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
Feb-23-2021 15:18:27 (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  <i>If Other, specify:</i>  Unopposed ERT	New Information

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Feb-23-2021 15:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-23-2021 15:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 15:12:43 (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
Feb-23-2021 15:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Mar-09-2021 05:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SDB updated
Mar-08-2021 02:06:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Pending SDB update
Mar-04-2021 16:18:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Submitted today!
Mar-03-2021 15:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON1: Thanks for the response. Please confirm submission of SAE follow up form.
Mar-03-2021 09:17:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This will be submitted to Safety.

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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

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791076

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Mar-02-2021 02:59:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	SAE RECON 1: outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB. Please submit a follow up form to update outcome in Safety database to RECOVERING/RESOLVING per previous query response.
Mar-01-2021 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is still recovering from cancer.
Feb-26-2021 00:23:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021187485,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-23-2021 15:12:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECOVERING	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

			/RES OLVI NG	
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-23-2021 15:12:43 (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
Feb-24-2021 03:38:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021187485	Initial Entry

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**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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-21-2021 16:49:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	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:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Jan-21-2021 16:49:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 16:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-21-2021 16:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccina tion 3 Participant is:  eligible and NOT confirmed to hav e received only pl acebo at Vaccinat ion 1/2	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

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

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

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-21-2021 16:49:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-21-2021 16:49:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Subject Status**

Date	Location	User	Value	Reason
Sep-29-2020 16:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-07-2020 14:20:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZ ED	Initial Entry
Aug-07-2020 14:13:55 (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
Feb-23-2021 18:40:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 15:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-23-2021 09:23:01 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE report (#2021187485)

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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**Form Status:** Data Complete, Verified

**Site No:** 1079

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject No:** 10791076

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Eastern Time (US & Canada)				received for event Uterine Cancer; please report this event on the AE CRF
Sep-29-2020 16:32:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/29/2020	Initial Entry
Aug-07-2020 14:20:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/7/2020	Initial Entry
Aug-07-2020 14:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1079

**Subject No:** 10791076

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

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

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

**Site Name:** (1079) PMG Research of Charlotte LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Casebook Signature**

Date	Location	User	Value	Reason
Sep-10-2020 15:40:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae2f25\Final\Final On: 01-Apr-2021 03:36 (GMT)