

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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 Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/3/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[10791044]
2.	Birth Date:	(b) (6) /1948
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: 10791044

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/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1079

Subject No: 10791044

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: 10791044

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/3/2020
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: 10791044

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:	[Insomnia]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic Rhinitis - Seasonal]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Internal Hemorrhoids - Stage 1]
	Start Date:	Jun/18/2020
	Ongoing:	YES

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Menopause]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperpigmentation ON SKIN]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/1964
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis - Bilateral Knees]
	Start Date:	UNK/UNK/2018
	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: 10791044

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/3/2020
2.	Weight:	[72.8]
3.	Unit:	kg
4.	Height:	[161.0]
5.	Unit:	cm
6.	Body Mass Index:	[28.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.1]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1079**Subject No:** 10791044**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 _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

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/3/2020
2.	Randomization Number:	[221821]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/3/2020
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	[BMPYFV]
5.b	Sample ID	[BMPYFW]
5.c	Sample ID	[BNBCDX]
5.d	Sample ID	[BNBCDY]
5.e	Sample ID	[BNBCDZ]

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/3/2020
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	[BNBCD2]
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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791044

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/3/2020 16:05
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

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1079

Subject No: 10791044

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: 10791044

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/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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 Symptoms Diary - Symptom Resolved Dates

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

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

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
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

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

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/25/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
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	[BPXVJ9]
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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791044

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/25/2020 15:05
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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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	Oct/2/2020
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: 10791044

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
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

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/2/2020
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	[BLG0TY]
5.b	Sample ID	[BLG0TF]
5.c	Sample ID	[BPB0PN]

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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/24/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
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	[BRN1J7]
5.b	Sample ID	[BS238L]
5.c	Sample ID	[BS237G]

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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 Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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 Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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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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: 10791044

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:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

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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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

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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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: 10791044

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?	
----	--	--

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: 10791044

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: 10791044

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

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: 10791044

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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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: 10791044

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: 10791044

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 Version: 15-Sep-2020 21:55

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

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 - Treatment

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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 - New
Unscheduled Visit

Form: DATE OF VISIT - 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: 10791044

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:	
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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

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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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: 10791044

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	Worsening of Osteoarthritis Bilateral Knee	Oct/5/2020 UNK:UNK	NO End Date Time: Dec/7/2020 UNK:UNK	Repeating Pages

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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)	[Worsening of Osteoarthritis Bilateral Knee]
4.	Start Date Time:	Oct/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/7/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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: [OA of Knee]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021206922]

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.	MEDICATION ERROR	Administration of correct study intervention from incorrect container (product administration error)	Aug/3/2020	NO End Date: Aug/3/2020	NO ACTION TAKEN	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: MEDICATION ERROR

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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[Form Audit Trail](#)

Medication Error

1.	Category:	MEDICATION ERROR
2.	Medication Error (Type of Medication Error):	[Administration of correct study intervention from incorrect container (product administration error)]
3.	Start Date:	Aug/3/2020
4.	Is the medication error still ongoing?	NO End Date: Aug/3/2020
5.	Latest Action Taken with Study Treatment:	NO ACTION TAKEN
6.	Was a Concomitant Medication given?	NO
7.	Was a Non-Drug Treatment given?	NO
8.	Did the Medication Error cause the subject to be discontinued from the study?	NO
9.	Was this medication error associated with any adverse events?	NO
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

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:	//

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

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?	

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

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: 10791044

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: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

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:	

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

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: 10791044

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?	

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

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: 10791044

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: 10791044

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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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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: 10791044

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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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: 10791044

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: 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: 10791044

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	Feb/22/2021
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: 10791044

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 Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

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](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, 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](#)

Withdrawal Of Consent

			Comments
1.	Withdrawal of Consent Date :	Not Applicable _____ //	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, 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](#)

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	Comments
----	---	-------------------------------	--------------------------

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

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

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: 10791044

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: 10791044

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 17:26:21 (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.

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1079

Subject No: 10791044

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 16:04:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
1	Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 30-Jul-2020 21:27
Site No: 1079
Subject No: 10791044
Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
2	Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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Item	Date	User	Comment
3	Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
4	Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
5	Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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Item	Date	User	Comment
6.a	Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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Item	Date	User	Comment
6.a	Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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Item	Date	User	Comment
3	Aug-26-2020 17:23:49 (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: 10791044

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 09:14:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Oct-02-2020 16:32:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, 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	Feb-22-2021 16:34:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, 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
1	Feb-22-2021 16:34:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, 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	Feb-22-2021 16:35:06 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

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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Item	Date	User	Comment
1	Feb-22-2021 16:35:06 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
George Raad	Approved	Mar-10-2021 17:26:21 (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 16:33:40 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

George Raad	Approved	Jan-22-2021 10:06:14 (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.

(b) (6)	N/A	Dec-03-2020 09:37:59 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

George Raad	Approved	Oct-27-2020 12:57:59 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

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	Oct-23-2020 09:14:26 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

George Raad	Approved	Oct-12-2020 11:03:13 (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	Oct-02-2020 16:30:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

George Raad	Approved	Sep-16-2020 14:31:23 (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.

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1079

Subject No: 10791044

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-04-2020 08:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 08:41:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - 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. Consent Was:

Date	Location	User	Value	Reason
Aug-04-2020 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/3/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1079

Subject No: 10791044

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-04-2020 08:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10791044	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-04-2020 08:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1948	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-04-2020 08:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-04-2020 08:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 08:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERIC AN	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-04-2020 09:03:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - 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. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-04-2020 09:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-04-2020 09:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-04-2020 09:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1079**Subject No:** 10791044**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - 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](#)**I.a**

Date	Location	User	Value	Reason
Aug-04-2020 09:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Insomnia Start Date: UNK/UNK/2007 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 09:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Insomnia	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2007	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 09:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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-04-2020 09:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Hypertension Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 09:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 09:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-04-2020 09:04:33 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Time (US & Canada)			ber: Medical Histor Allergic Rhinitis - y Term: Seasonal Start Date: UNK/UNK/2015 Ongoing: YES
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 09:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergic Rhinitis - Seasonal	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 09:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-04-2020 09:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 4 mber: Medical Histo Internal Hemorrh ry Term: ids - Stage 1	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Start Date: Jun/18/2020	
			Ongoing: YES	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 09:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Internal Hemorrhoids - Stage 1	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/18/2020	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 09:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-04-2020 09:05:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Menopause Start Date: UNK/UNK/1 995 Ongoing: YES	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:05:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 09:05:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Menopause	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:05:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 09:05:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-04-2020 16:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 6 Medical History Term: Hyperpigmentation ON SKIN Start Date: UNK/UNK/1980 Ongoing: YES	New Information
Aug-04-2020 09:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Medical History Term:	Hyperpigmentation	
			Start Date:	UNK/UNK/1980	
			Ongoing:	YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 17:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-04-2020 16:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-04-2020 16:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperpigmentation ON SKIN	New Information
Aug-04-2020 11:57:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify HYPERPIGMENTATION as follows...Term is unclear. Are you reporting HYPERPIGMENTATION SKIN? Or BONE HYPERPIGMENTATION? Or INJECTION SITE HYPERPIGMENTATION? Or other? Please edit the term to clarify. Thank you.
Aug-04-2020 09:06:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyper	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Eastern Time (US & Canada)			pigmin tation	
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I.f Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 09:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-04-2020 09:07:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Asthma Start Date: UNK/UNK/1 964 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:07:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 09:07:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Asthma	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:07:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1964	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 09:07:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-04-2020 09:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Osteoarthritis - Bilateral Knees Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 09:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis - Bilateral Knees	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 09:07:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 161.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.1	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

7.a

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.1 Temperature Unit: F Temperature Locat FOREHE ion:: AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

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-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier:	Not Applicable
			Test:	Not Applicable
			Result:	Not Applicable
			Not Done:	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-04-2020 09:08:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

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-04-2020 09:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-04-2020 09:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 221821	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

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-04-2020 09:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-04-2020 09:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-04-2020 09:27:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-04-2020 09:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-04-2020 09:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/3/2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-06-2020 09:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Aug-05-2020 18:23:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPDATED
Aug-05-2020 06:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Opened	Please can you confirm the amount of blood drawn, as there are only 2 serum samples showing below. If blood was not drawn per protocol, please update Q4 as appropriate. Thanks

5.a

Date	Location	User	Value	Reason
Aug-04-2020 09:27:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMPYFV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 09:27:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPYFV	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-04-2020 09:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMPYFW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 09:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPYFW	Initial Entry

5.c

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-05-2020 18:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNBCDX	Transcription Error
Aug-05-2020 18:22:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNBCDXH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-05-2020 18:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNBCDX	Transcription Error
Aug-05-2020 18:22:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Aug-05-2020 18:22:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNBCDXH	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-05-2020 18:22:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNBCDY	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:22:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNBCDY	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

5.e

Date	Location	User	Value	Reason
Aug-05-2020 18:22:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNBCDZ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:22:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNBCDZ	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:** 10791044**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
Aug-04-2020 09:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-04-2020 09:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-04-2020 09:09:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-04-2020 09:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-04-2020 09:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-04-2020 09:09:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNBCD2	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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-04-2020 09:09:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNBCD2	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791044

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020 16:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791044

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

7. Route:

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 09:10:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - 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 - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-02-2020 04:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 1: Closed	Raised on wrong subject
Sep-02-2020 03:43:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes' however VAX 1 eDiary records are not available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-04-2020 09:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E -DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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-26-2020 17:18:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	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: 10791044

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
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the la O st day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

			E	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.b Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-26-2020 17:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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:** 10791044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05**2.c Symptom:**

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the l O ast day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSE NED MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NEDED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NEDED 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-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW : ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

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-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1079**Subject No:** 10791044**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - 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. Date:**

Date	Location	User	Value	Reason
Aug-26-2020 17:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-26-2020 17:23:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 98.2 Temperature Unit: F Temperature Loca tion:: FOREHE AD	Initial Entry
Aug-26-2020 17:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: Temperature Location::	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 17:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-26-2020 17:23:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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-26-2020 17:23:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry
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2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-26-2020 17:23:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

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3. Collection Date:

Date	Location	User	Value	Reason
Aug-26-2020 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-26-2020 17:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX1 13 Result:: Not Done:: NOT DONE	Initial Entry
Aug-26-2020 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX1 13 Result:: Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-26-2020 17:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Aug-26-2020 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX1 13	Initial Entry
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6.a Not Done:

Date	Location	User	Value	Reason
Aug-26-2020 17:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

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-26-2020 17:24:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-26-2020 17:24:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-26-2020 17:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-26-2020 17:24:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 17:24:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 17:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPXVJ9	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 17:24:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXVJ9	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791044

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 15:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791044

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

7. Route:

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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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I. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 05:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker
Oct-06-2020 15:33:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was out of window - unable to come in due to transportation issues
Oct-06-2020 10:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (3 day) from DOV (25/Aug /2020) at V2_VAX2_L. Please reconcile and update accordingly, else confirm date is correct as is.
Oct-02-2020 16:30:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

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
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary w as completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

			E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-23-2020 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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:** 10791044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05

Oct-23-2020 09:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-23-2020 09:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
Oct-23-2020 09:14:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-22-2020 18:34:34 (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.
Oct-02-2020 16:32:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti ons present on the last da y the Subject Diary was c ompleted?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	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:** 10791044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary wa s completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reactio PAIN A n:: T INJE CTION SITE	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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

			Were injection site re NO actions present on the last day the Subject D iary was completed?:	
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 16:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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:** 10791044**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
Oct-02-2020 16:32:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-02-2020 16:32:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-02-2020 16:37:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 16:32:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-02-2020 16:32:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-02-2020 16:37:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLG0TY	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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 16:37:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLG0TY	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-02-2020 16:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLG0TF	Transcription Error
Oct-02-2020 16:38:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLGPTF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 16:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLG0TF	Transcription Error
Oct-02-2020 16:38:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLGPTF	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-02-2020 16:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPB0PN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 16:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPB0PN	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

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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I. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 17:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/24/2021	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: 10791044

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-25-2021 17:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 17:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-25-2021 17:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 17:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 17:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/24/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-25-2021 17:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRN1J7	Initial Entry

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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: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 17:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRN1J7	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-25-2021 17:45:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS238L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 17:45:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS238L	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-25-2021 17:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS237G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 17:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS237G	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - 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 Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-05-2020 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-05-2020 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-05-2020 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Mar-02-2021 17:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry
Mar-02-2021 17:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-02-2021 17:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry
Mar-02-2021 17:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-04-2021 01:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-03-2021 16:59:59 (UTC-05:00) Eastern Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

(US & Canada)				
Mar-03-2021 14:23:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Mar-03-2021 14:23:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-03-2021 14:23:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of Osteoarthritis Bilateral Knee	Changed Information
Mar-03-2021 03:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Multiple concepts in the term OSTEOARTHRITIS RESULTED IN A TOTAL KNEE REPLACEMENT. Please split the term into OSTEOARTHRITIS IN KNEE and TOTAL KNEE REPLACEMENT and submit separately. Thank you.
Mar-02-2021 23:11:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clinical - Surgery procedure not required in SAE event term (procedure reported in serious event narrative). Please update event term to

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

				a non-surgical term (in AE and SAE)
Mar-02-2021 17:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis resulted in a total knee replacement	Transcription Error
Mar-02-2021 17:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Knee Replacement	Initial Entry
Mar-02-2021 17:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-02-2021 17:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-02-2021 02:37:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021206922, term reported as Total Right knee Replacement in both database. Per CRF completion guidelines, please avoid use of a procedure for the AE event name; please review and enter the AE term for which the procedure was performed.

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (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, Frozen

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Total Right knee Re- placement	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/7/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-04-2021 12:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-03-2021 14:25:55 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Will have this sent to safety.

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

Time (US & Canada)		(b) (4), (b) (6)		
Mar-02-2021 23:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021206922] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Mar-02-2021 02:33:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Total Right knee Replacement: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

			<p>persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	---	--

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

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

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: OA of Knee	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 16:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-02-2021 02:33:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2021206922	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: MEDICATION ERROR - Audit Trail

Form Status:

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Dec-03-2020 09:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: MEDICATION ERROR - 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. Category:

Date	Location	User	Value	Reason
Dec-03-2020 09:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: MEDICATION ERROR	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Dec-03-2020 09:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Administration of correct study int ervention from incorrect container (product administration error)	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Dec-03-2020 11:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/3/2020	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
Dec-03-2020 11:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Aug/3/2020	Initial Entry

5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-03-2020 11:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO ACTION TAKEN	Initial Entry

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

Dec-03-2020 11:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-03-2020 11:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-03-2020 11:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Dec-03-2020 11:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

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
Feb-22-2021 16:33:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/22/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

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 - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-24-2021 08:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Feb-22-2021 16:33:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 20:43:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Feb-24-2021 08:38:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-24-2021 08:38:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Feb/22/2021	Transcription Error
Feb-24-2021 04:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7391059;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-22-2021 16:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Feb/16/2021	Initial Entry

2. Primary Reason for Unblinding:

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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

Date	Location	User	Value	Reason
Mar-04-2021 12:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Mar-01-2021 16:15:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swere d	This has been entered!
Feb-28-2021 21:18:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	Clinical - SAE report for Rt knee surgery on 06Oct20 received; please enter this event on the AE log CRF
Feb-24-2021 15:03:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Clo sed	Response satisfies query
Feb-24-2021 08:40:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Changed data per query
Feb-24-2021 03:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7390903;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF.

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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

				Please review and update as appropriate.
Feb-22-2021 16:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : ASSE SS EL IGIBI LITY FOR ADDI TION AL V ACCI NATI ON	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - 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. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-22-2021 16:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: DEATH DETAILS CODED - 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 Collection / Notification of Death:

Date	Location	User	Value	Reason
Feb-22-2021 16:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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I. Subject Status

Date	Location	User	Value	Reason
Jan-11-2021 19:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-08-2021 09:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	I put this in as i was told to by study sponsor. There is nothing to change
Nov-30-2020 20:04:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please note medication error CRF should match the deviation reported for subject. Please review the suggested text and update CRF if appropriate: Administration of correct study intervention from incorrect container(product administration error)
Oct-05-2020 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-04-2020 09:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-04-2020 09:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-02-2021 02:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791044

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

Mar-01-2021 17:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-26-2021 04:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021206922 total right knee replacement was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. Per CRF completion guidelines, please avoid use of a procedure for the AE event name
Oct-05-2020 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Initial Entry
Aug-04-2020 09:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/3/2020	Initial Entry
Aug-04-2020 09:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/3/2020	Initial Entry

090177e196ae2f23\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791044

Subject Initials: ---

Generated By: (b) (4)

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-10-2020 15:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry