

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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
.	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: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Informed Consent

.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/10/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10801006]
2.	Birth Date:	(b) (6) 1946
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Form Comments

Inclusion Criteria Not Met

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/10/2020
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: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Glaucoma - right eye]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroid]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vaginal Dryness]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurrent Panic Attack]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

1 f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vaginal dry Skin]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/10/2020
.	Weight:	[76.3]
.	Unit:	kg
.	Height:	[169.0]
.	Unit:	cm
6.	Body Mass Index:	[26.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/10/2020
2.	Randomization Number:	[224990]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/10/2020
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	[BP59TT]
5.b	Sample ID	[BP59TV]
5.c	Sample ID	[BP59TW]
5.d	Sample ID	[BPRN5F]
5.e	Sample ID	[BPRN5G]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/10/2020
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	[BP59FM]
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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/10/2020 16:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[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?	YES Ongoing? NO Stop Date: Aug/31/2020
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?	YES Ongoing? NO Stop Date: Aug/31/2020

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/31/2020
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:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/31/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP59L6]
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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/31/2020 15:36
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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[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?	YES Ongoing? NO Stop Date: Sep/8/2020
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?	YES Ongoing? NO Stop Date: Sep/8/2020
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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.g	Symptom:	NEW OR WORSENER MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENER JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTSPF]
5.b	Sample ID	[BRT45F]
5.c	Sample ID	[BRT45G]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Nov/24/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/24/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/24/2020
2.	Date of First Symptom Started:	Oct/13/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Nov/25/2020

Symptoms

.a	Symptoms:	FEVER
	Was symptom present?	NO
.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
.d	Symptoms:	CHILLS
	Was symptom present?	NO
.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4 f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4 i	Symptoms:	VOMITING
	Was symptom present?	YES

ymptoms - Other

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.a

Symptoms - Other Text:

[Nausea]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Nov/24/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
.	Sample Collected?	YES Date of Collection: Nov/24/2020
4	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

.a	Sample ID	[CV11449]
----	-----------	-----------

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3	Sample Collected?	NO
	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Self-swab was collected]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Nov/24/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Nov/24/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	est:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Nov/24/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details		Form Instance
1		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Nov/24/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Dec/22/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/22/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Dec/22/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
.	Sample Collected?	YES Date of Collection: Dec/22/2020
4	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

.a	Sample ID	[BPTSLS]
5.b	Sample ID	[BPRCBC]
5.c	Sample ID	[BPRCBD]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/17/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/17/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/17/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/17/2020 Contact Outcome: VISIT NOT ARRANGED, REACTION NO LONGER PRESENT
3.	Comments:	[Called patient, Grade 3 temperature reaction no longer present.]

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/19/2020 Contact Outcome: VISIT ARRANGED
3.	Comments:	[]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form: VITAL SIGNS - TEMP

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/19/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC
EVENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Unplanned Assessment Of Local Reaction

1.	Date of Assessment:	Aug/19/2020
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	RIGHT

Reaction

.a	Reaction:	REDNESS
	Reaction Present:	NO
.b	Reaction:	SWELLING
	Reaction Present:	NO

Symptom

5 a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	NO
.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	NO
.c	Symptom:	HEADACHE
	Symptom Present:	NO
.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	YES
		Symptom Grade: 1
		Event related to Study Treatment? NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC
EVENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5.f	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Symptom Present:	YES Symptom Grade: 1 Event related to Study Treatment? NO
5.g	Symptom:	NEW OR WORSENERD JOINT PAIN
	Symptom Present:	NO
5.h	Symptom:	CHILLS
	Symptom Present:	NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/28/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	Redness at injection site	Aug/10/2020 16:08	NO End Date Time: Aug/10/2020 17:08	Repeating Pages
2.	ADVERSE EVENT	2	Swelling at injection site	Aug/10/2020 16:08	NO End Date Time: Aug/10/2020 17:08	Repeating Pages
3.	ADVERSE EVENT	3	Lower Back Pain	Aug/14/2020 08:00	NO End Date Time: Aug/17/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Nausea	Aug/10/2020 16:37	NO End Date Time: Aug/10/2020 17:08	Repeating Pages
5.	ADVERSE EVENT	5	Intermittent Diarrhea	Aug/12/2020 UNK:UNK	NO End Date Time: Aug/19/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Chills	Aug/13/2020 UNK:UNK	NO End Date Time: Aug/14/2020 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	Headache	Sep/8/2020 UNK:UNK	NO End Date Time: Sep/28/2020 UNK:UNK	Repeating Pages

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

	Category:	ADVERSE EVENT
.	AE ID:	[1]
.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Redness at injection site]
4.	Start Date Time:	Aug/10/2020 16:08
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/10/2020 17:08
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Swelling at injection site]
4.	Start Date Time:	Aug/10/2020 16:08
.	Is the adverse event still ongoing?	NO End Date Time: Aug/10/2020 17:08
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9	Is this event related to study treatment:	RELATED
0.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
1.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Lower Back Pain]
4.	Start Date Time:	Aug/14/2020 08:00
.	Is the adverse event still ongoing?	NO End Date Time: Aug/17/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Nausea]
4.	Start Date Time:	Aug/10/2020 16:37
.	Is the adverse event still ongoing?	NO End Date Time: Aug/10/2020 17:08
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
0.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
1.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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	[]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Intermittent Diarrhea]
4.	Start Date Time:	Aug/12/2020 UNK:UNK
.	Is the adverse event still ongoing?	NO End Date Time: Aug/19/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Aug/13/2020 UNK:UNK
.	Is the adverse event still ongoing?	NO End Date Time: Aug/14/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Sep/8/2020 UNK:UNK
.	Is the adverse event still ongoing?	NO End Date Time: Sep/28/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
0.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
1.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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	[]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Medication Error

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	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 Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	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: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	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: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Vital Signs

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

Vital Signs Details

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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:	

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
.	Body Side:	
.	Route:	
.	Actual Dose:	[]
.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/25/2021
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: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Withdrawal Of Consent

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

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

Cause of Death

·	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/26/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/26/2021
---	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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 _____
----	---	-------------------------

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/26/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/26/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/26/2021
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	[BR9R85]
5.b	Sample ID	[BRT3W9]
5.c	Sample ID	[BRT3W8]

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/26/2021
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	[BR9R8C]
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/26/2021 10:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/16/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/16/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/16/2021
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	[BR9RCN]
-----	-----------	----------

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/16/2021 09:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Casebook Signature Form

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

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

tem	Date	User	Comment
orm	Aug-11-2020 18:08:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Met all criteria
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
7	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
8	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
9	Dec-01-2020 14:20:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
- Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-27-2021 13:32:29 (UTC-05:00) Eastern Time (US & Canada)	Mollie Maples (b) (4)	Not Applicable

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Mo aples	N/A	Jan-27-2021 13:31:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - A signatur invalida

Affidavit:
N/A

Sylvia Shoffner	Approved	Jan-21-2021 16:28:02 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, SylviaShoffner, 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-01-2020 14:17:06 (UTC-05:00) Eastern Time (US & Canada)		Edit - A signatur invalida
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Affidavit:
N/A

Sylvia Shoffner	Approved	Oct-13-2020 20:12:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Oct-13-2020 16:45:33 (UTC-05:00) Eastern Time (US & Canada)		Edit - Al signature invalidat
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Affidavit:

N/A

Sylvia Shoffner	Approved	Oct-12-2020 12:47:23 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, SylviaShoffner, 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)	A	Sep-28-2020 17:15:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - A signatur invalida
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Affidavit:

N/A

Sylvia Shoffner	Approved	Sep-14-2020 11:03:29 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, SylviaShoffner, 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.

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-11-2020 08:06:39 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-10-2020 18:17:30 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-10-2020 18:15:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-10-2020 18:14:53 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: 10801006	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-10-2020 18:14:48 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	auto c lc (utocalc)	Data Entry: (b) (6)/1946	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-10-2020 18:15:31 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-10-2020 18:15:31 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-10-2020 18:15:34 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-10-2020 18:18:11 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-10-2020 18:20:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-10-2020 18:20:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (a ocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-10-2020 18:20:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-10-2020 18:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Glaucoma - right eye Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 18:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: 1	nitial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 18:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Glaucoma - right eye	nitial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 18:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	nitial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 18:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	nitial Entry

I.b

Date	Location	User	Value	Reason
Aug-10-2020 19:00:39	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH Number: 2 Medical History Term: Hypothyroidism Start Date: UNK/UNK/2010 Ongoing: YES	
---	--	------------	---	--

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 19:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 19:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypothyroid	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 19:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 19:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-10-2020 19:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Vaginal Dryness Start Date: UNK/UNK/2010	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Ongoing:	YES	
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 19:01:10 (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-10-2020 19:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vaginal Dryness	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 19:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 19:01:10 (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-10-2020 19:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Depression Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 19:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	<u>Data Entry:</u> 4	nitial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 19:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Depression	nitial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 19:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1995	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 19:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-11-2020 08:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Line/MH Number: 5 er: Medical History: Recurrent Panic Term: Attack Start Date: UNK/UNK/2014 Ongoing: YES	Subject did not express having panic attack within 48 hours of vaccination.
Aug-10-2020 19:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 5 Medical History Term: Panic Attack rm:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Start Date:	UNK/UNK/2 014	
			Ongoing:	YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 19:03:17 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 10:51:58 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Hayley Wype (b) (4)	Query 1: Closed	Response satisfies query
Aug-11-2020 08:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	au o que y (autoque y)	Query 1: Answered	Subject did not express having panic attack within 48 hours of vaccination.
Aug-11-2020 08:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Recurrent Panic Attack	Subject did not express having panic attack within 48 hours of vaccination.
Aug-11-2020 07:29:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	GPD Clin: Panic Attack is reported to be ongoing since 2014. Please clarify in event term if this is a RECURRENT event since 2014 and, if so, confirm symptoms not present within 48h of vaccination if symptoms could meet delaying criteria.
Aug-10-2020 19:03:17 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Panic Attack	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 19:03:17 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.e Ongoing:

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-10-2020 19:03:17 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	initial Entry

If

Date	Location	User	Value	Reason
Aug-10-2020 19:03:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Vaginal dry Skin Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

If Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 19:03:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: 6	nitial Entry

If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-10-2020 19:03:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: V ginal dry Skin	In tial Entry

If Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 19:03:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	nitial Entry

If Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 19:03:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	In tial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 76.3	In tial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	nitial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 169.0	In tial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	nitial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: 26.7	nitial Entry

7.a

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.4 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 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-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-10-2020 19:10:28 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-10-2020 19:08:15 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-10-2020 19:08:15 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-10-2020 19:08:15 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Aug/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-10-2020 19:08:15 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-10-2020 19:08:15 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-10-2020 19:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Test::	Choriogonadotropin Beta_PX113
			Result::	
			Not Done::	NOT DONE

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-10-2020 19:08:15 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocale)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-10-2020 19:08:15 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-12-2020 09:12:16 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Query N/A due to age
Aug-12-2020 06:41:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	GPD Clin: Please confirm why a pregnancy test was not done. There is nothing in her medical history to indicate she is not a woman of child bearing potential. Please update MedHx as appropriate.
Aug-10-2020 19:08:15 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-11-2020 08:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-12-2020 14:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_07
Aug-12-2020 07:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-12-2020 07:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 224990	Transcription Error
Aug-12-2020 04:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4174932;Randomization Number appears to be a duplicate with Subject 10801007. Please confirm the number has been entered correctly or clarify.
Aug-11-2020 08:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 224991	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-10-2020 18:47:52 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-10-2020 18:47:52 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-10-2020 18:48:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 18:47:52 (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-10-2020 18:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/10/2020	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-10-2020 18:48:59 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-10-2020 18:48:38 (UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRN5G	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject No:** 10801006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**5.a**

Date	Location	User	Value	Reason
Aug-10-2020 18:48:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP59TT	initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 18:48:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	D a Entry: BP 9TT	initial Entry

5.b

Date	Location	User	Value	Reason
Aug-10-2020 18:48:10 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	D a Entry: S mple ID: BP59TV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 18:48:10 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	D a Entry: BP 9TV	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-10-2020 18:48:19 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP59TW	initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 18:48:19 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	D a Entry: BP 9TW	initial Entry

5.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Aug-10-2020 18:48:29 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPRN5F	Initial Entry
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5.d Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 18:48:29 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRN5F	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-10-2020 18:49:07 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPRN5G	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 18:49:07 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRN5G	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-10-2020 18:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a calc (au ocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-10-2020 18:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-10-2020 18:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a o query (toquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 18:49:19 (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-10-2020 18:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-10-2020 18:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP59FM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Aug-10-2020 18:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP59FM	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-10-2020 19:06:41 (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-10-2020 19:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a calc (au ocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-10-2020 19:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-21-2020 07:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-20-2020 17:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Form updated
Aug-20-2020 09:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM 1: Please update "Contact Outcome" form under unplanned visit.
Aug-18-2020 1 :31:25 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was contacted. Please confirm if

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Eastern Time (US & Canada)				unplanned contact is the same as unplanned visit form
Aug-18-2020 03:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Subject has reported with Severe symptoms/reactions on '2020-08-14'. Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. (b) (4)
Aug-10-2020 19:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020 16:08	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-10-2020 19:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (utocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-10-2020 19:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-10-2020 19:06:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-10-2020 19:06:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	nitial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 19:06:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	nitial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-10-2020 19:05:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 21:10:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
ep-12-2020 03:07:40 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated per query
ep-11-2020 16:56:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	auto query (query)	Query 1: Answered	subject did not have fever on day of Vaccination day 2.
Sep-11-2020 16:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/31/2020	Subject did not have fever on day of Vaccination day 2.
Sep-10-2020 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ: Per Diary records, Medication for fever or pain is not ongoing on 31Aug20 which is Day 1 of VAX2. Please reconcile and update as stop data. Else, clarify in query response. Thanks.
ep-09-2020 13:15:47 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ever and pain is ongoing
Sep-07-2020 13:24:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 1: Opened	eDiary: Vaccination 2 is given for the subject, however FEVER/PAIN MED associated with Vaccination 1 is still ongoing. Please review and update as appropriate. Else, clarify in query response.

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? YES	Initial Entry
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2.a

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IGU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	CH ILL S NO
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2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry VO MITI NG NO

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-09-2020 19:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing ? NO Stop Date: Aug /31/ 202 0	Subject reported that AE's were not present during vaccination 2. They were gone by morning of vaccination.
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIAR RHEA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? YES S	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-10-2020 12:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-09-2020 19:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Subject reported that AE's were not present during vaccination 2. They were gone by morning of vaccination.
Sep-09-2020 19:27:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/31/2020	Subject reported that AE's were not present during vaccination 2. They were gone by morning of vaccination.
Sep-07-2020 13:25:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 1: Opened	eDiary: Vaccination 2 is given for the subject, however DIARRHEA associated with Vaccination 1 is still ongoing. Please review and update as appropriate. Else, clarify in query response.
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? YES	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.g

Date	Location	User	Value	Reason
Sep-09-2020 19:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Aug/31/2020	Subject reported that AE's were not present during vaccination 2. They were gone by morning of vaccination.
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE MUSCLE PAIN Were fever or system ic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? YES	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MUSCLE PA IN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 11:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-09-2020 19:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Subject reported that AE's were not present during vaccination 2. They were gone by morning of vaccination.
Sep-09-2020 19:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/31/2020	Subject reported that AE's were not present during vaccination 2. They were gone by morning of vaccination.
Sep-07-2020 13:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (b) (4)	Query 1: Opened	eDiary: Vaccination 2 is given for the subject, however NEW OR WORSENERD MUSCLE PAIN associated with Vaccination 1 is still ongoing. Please review and update as appropriate. Else, clarify in query response.
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing?	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			YES	
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2.h

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE ED JOINT PAIN Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
ep-01-2020 17:52:30 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	nitial Entry

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

Date	Location	User	Value	Reason
ep-01-2020 17:52:30 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
ep-01-2020 17:52:30 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
ep-01-2020 17:52:30 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.a

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions p resent on the last day the Subj ect Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLIN G Were injection site reactions present on the last day the Su bject Diary was completed?: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 17:52:30 (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
Sep-01-2020 17:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-31-2020 21:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-31-2020 21:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Location:: ORAL CAVIT Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 21:11:23 (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-31-2020 21:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-31-2020 21:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-31-2020 21:11:23	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

(b) (4), (b) (6) ORAL CAVITY

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-31-2020 21:11:43 (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-31-2020 21:11:43 (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-31-2020 21:11:43 (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-31-2020 21:11:43 (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-31-2020 21:11:43 (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-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 21:11:43 (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-31-2020 21:11:43 (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-31-2020 21:11:43 (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-31-2020 21:11:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 21:12:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocale)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 21:12:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 21:12:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 21:12:18 (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-31-2020 21:12:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 21:12:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP59L6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Aug-31-2020 21:12:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP59L6	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-31-2020 21:13:36 (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-31-2020 21:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a calc (au ocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-31-2020 21:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-31-2020 21:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020 15:36	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 21:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-31-2020 21:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-31-2020 21:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-31-2020 21:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 21:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 05:50:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-07-2020 15:00:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-07-2020 05:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Kindly consider to update details on SYMPRDATE form or else clarify. Thank you.
Sep-29-2020 12:56:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Sep-29-2020 12:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EOT tab is complete
Sep-29-2020 10:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Since subject has now completed V3 and the treatment period of the study, please complete the EOT tab to indicate 'Completed'
Sep-28-2020 17:15:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/28/2020	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-09-2020 03:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 16:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Sep/8/2020	Transcription Error
Oct-08-2020 16:51:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	au query (a oquery)	Query 1: Answered	Transcription Error
Oct-08-2020 16:51:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Sep/28/2020	Transcription Error
Oct-08-2020 00:58:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, FEVER/PAIN MED present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: N	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.a

Date	Location	User	Value	Reason
Oct-09-2020 13:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Changed Information
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing ? NO Stop Date: Sep /28/ 202 0	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 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-09-2020 15:14:10 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-09-2020 13:49:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	uto query autoquery)	Query 1: Answered	Changed Information

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080
Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary
Subject No: 10801006
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:11

Oct-09-2020 13:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	hanged Information
Oct-09-2020 03:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ1: Per CCG, if eDiary is missing and if deemed appropriate by PI, reactogenicity events that are not reported in the e-diary in error can be moved to the AE CRF. Please reconcile and update as appropriate. Thanks.
Oct-08-2020 16:52:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject expressed having a fever in person.
Oct-08-2020 03:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, FEVER not present on Last day however inform is entered with 'Yes' for the same. Please verify and update. Else, clarify. Thanks.
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Sep/28/2020	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IG UE	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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			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-07-2020 15:00:09 (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
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-08-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date : Sep /8/ 2020	Transcription Error
Oct-08-2020 16:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE	Transcription Error

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing ? NO</p> <p>Stop Date: Sep /28/ 202 0</p>	
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom::</p> <p>HEA DAC HE</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>NO</p>	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.c Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 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-09-2020 07:11:50 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies uery
Oct-08-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Sep/8/2020	Transcription Error
Oct-08-2020 16:53:26 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	au query (a oquery)	Query 1: Answered	ranscription Error
Oct-08-2020 16:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Sep/28/2020	Transcription Error
Oct-08-2020 00:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, HEADACHE present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary.

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

				Thanks.
Oct-07-2020 15:00:09 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-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH ILL S Were fever or systemic sympt oms present on the last day th e Subject Diary was complete d?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 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-07-2020 15:00:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last da y the Subject Diary was com pleted?:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject No:** 10801006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**2.e Symptom:**

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 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-07-2020 15:00:09 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-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: DIA RR HE A Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 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-07-2020 15:00:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	initial Entry

2.g

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENED MUSCLE P AIN	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-07-2020 15:00:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED JOIN T PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.h Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAI N	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-07-2020 15:00:09 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-07-2020 15:00:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed? :	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	REDNESS	
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 (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-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 (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-07-2020 15:00:09 (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-07-2020 15:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN A T INJEC TION SI TE	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

Date	Location	User	Value	Reason
Oct-07-2020 15:00:09 (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-07-2020 15:00:09 (UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
ep-28-2020 17:15:39 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
ep-28-2020 17:15:39 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (o calc	Data Entry: SERUM	nitial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
ep-29-2020 15:32:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (o query	Query 1: Closed	lose Auto Query
Sep-29-2020 06:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-28-2020 17:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-28-2020 17:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 15:32:55 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTSPF	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)

5.a Sample ID

Date	Location	User	Value	Reason
ep-29-2020 15:32:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTSPF	nitial Entry

5.b

Date	Location	User	Value	Reason
ep-29-2020 15:33:16 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRT45F	nitial Entry

5.b Sample ID

Date	Location	User	Value	Reason
ep-29-2020 15:33:16 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRT45F	nitial Entry

5.c

Date	Location	User	Value	Reason
ep-29-2020 15:33:30 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRT45G	nitial Entry

5.c Sample ID

Date	Location	User	Value	Reason
ep-29-2020 15:33:30 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRT45G	In tial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-01-2020 14:21:59 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery	Query 1: Deleted	lose Auto Query
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery	Query 2: Deleted	lose Auto Query
Dec-01-2020 14:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-01-2020 14:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-01-2020 14:17:04 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/24/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-01-2020 14:17:04 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	au calc (au ocalc	Data Entry: COVID_A	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/24/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/13/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
eb-03-2021 04:55:14 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
eb-02-2021 09:45:49 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (oquery)	Query 1: Answered	New Information
Feb-02-2021 09:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	<u>Data Entry:</u> NO Date of Last Symptom Resolved: Nov/25/2020	New Information
Feb-02-2021 06:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm the symptoms are still ongoing for this COVID Illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify.
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

4.a

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED D COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

4.c

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED S s: HORTNESS OF BREAT H Symptom NO Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

4.e

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom Present: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	nitial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

4.h

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject No:** 10801006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**4.h Symptoms:**

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: YES	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 14:18:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-01-2020 14:18:40 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Nausea	Initial Entry

5.a Symptoms - Other Text:

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Dec-01-2020 14:18:40 (UTC-05:00) Eastern Time (US & Canada)	A V0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nausea	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

7. Test Result:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-01-2020 14:20:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-01-2020 14:21:59 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-01-2020 14:21:59 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (o tocalc	Data Entry: NASAL_SWAB_SELF	nitial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-01-2020 14:22:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (o toquery	Query 1: Deleted	lose Auto Query
Dec-01-2020 14:21:59 (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.
Dec-01-2020 14:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-01-2020 14:22:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV11449	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Dec-01-2020 14:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV11449	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-01-2020 14:22:39 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-01-2020 14:22:39 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> NASAL_SWAB	nitial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-01-2020 14:22:39 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 14:22:39 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Self-swab was collected	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner EMERGENC : Y ROOM Occurrence of Visits NO or Contacts:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete**Site No:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject No:** 10801006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			Occurrence of Visits or NO Contacts:	
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I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Dec-01-2020 14:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Con NO tacts:	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 14:24:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/24/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Dec-01-2020 14:24:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-01-2020 14:24:41 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Dec/22/2020 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-23-2020 14:55:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-23-2020 14:55:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/22/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-23-2020 14:55:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-23-2020 14:55:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: SERUM	nitial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-23-2020 14:56:12 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery	Query 1: Deleted	lose Auto Query
Dec-23-2020 14:55:55 (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.
Dec-23-2020 14:55:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-23-2020 14:56:12 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTSLS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/22/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Dec-23-2020 14:56:12 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTSLS	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-23-2020 14:56:35 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPRCBC	nitial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-23-2020 14:56:35 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRCBC	nitial Entry

5.c

Date	Location	User	Value	Reason
Dec-23-2020 14:56:45 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPRCBD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-23-2020 14:56:45 UTC-05:00 Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRCBD	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/17/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-20-2020 17:19:14 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/17/2020	Transcription Error
Aug-20-2020 17:16:06 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>D a Entry:</u> Au /19/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/17/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Assessments

Date	Location	User	Value	Reason
Aug-20-2020 17:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	lose Auto Query
Aug-20-2020 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-20-2020 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/17/2020

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Aug-20-2020 17:19:27 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (a ocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Aug-20-2020 17:19:47 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	lose Auto Query
Aug-20-2020 17:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Aug/17/2020 Contact Outcome: VISIT NOT ARRANGED, REAC TION NO LONGER PRESENT	Transcription Error
Aug-20-2020 17:19:27 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of ontact" is missing.
Aug-20-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Contact Outcome: VISIT NOT ARRANGED, REAC TION NO LONGER PRESENT	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Aug-20-2020 17:20:38 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Called patient, Grade 3 temperature re action no longer present.	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-20-2020 17:21:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Assessments

Date	Location	User	Value	Reason
Aug-20-2020 17:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	lose Auto Query
Aug-20-2020 17:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-20-2020 17:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Aug-20-2020 17:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a calc (au ocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a o query (o query)	Query 1: Deleted	lose Auto Query
Aug-20-2020 17:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Aug-20-2020 17:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Aug/19/2020 Contact Outcome: VISIT ARRANGED	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001**Visit:** Unplanned 2 - Unscheduled Visit on
Aug/19/2020**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary**Subject No:** 10801006**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Aug-20-2020 17:22:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-20-2020 17:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location FOREHEA :: D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-20-2020 17:22:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	nitial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-20-2020 17:22:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.5	nitial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-20-2020 17:22:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Aug-20-2020 17:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry
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Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a to calc (utocalc)	Data Entry: DELTOID MUSCLE	nitial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

4.a

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: REDNESS Reaction Present:: NO	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	nitial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

4.b

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Reaction:: SWELLING Reaction Present:: NO	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: PAIN AT INJECTION SITE Symptom Present:: NO	Initial Entry

5.a Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5.b

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FATIGUE/TIRED NESS Symptom Present:: NO	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> N	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HEADACHE Symptom Present:: NO	Initial Entry

5.c Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5.d

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITING Symptom Present:: NO	Initial Entry

5.d Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRHEA Symptom Present:: YES Symptom Grade: 1 Event related to Study Treatment? NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC
EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of
Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5.e Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 1 Event related to Study Treatment? NO	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED MUSCLE PAIN Symptom YES Present:: Symptom Grade: 1 Event related to Study Treatment? NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5.f Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSCLE PAIN	initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
ep-10-2020 03:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wype (b) (4)	Query 1: Closed	Response satisfies query
ep-09-2020 19:12:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this AE is captured as lower back pain.
Sep-04-2020 07:40:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: NEW OR WORSENER MUSCLE PAIN G1 is reported as Not Related to Study Treatment. Please add this event to the AE log. Else, clarify if captured under another AE entry
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 1 Event related to Study Treatment? NO	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-13-2020 16:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENER JOINT PAIN Symptom P NO resent::	Transcription Error

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE D JOINT PAIN Symptom YES Present:: Symptom Grade: 2 Event related to Stud y Treatment? NO	Initial Entry
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Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5.g Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Oct-13-2020 16:45:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	ranscription Error
ep-10-2020 03:59:40 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Hayley Wype (b) (4)	Query 1: Closed	Response satisfies uery
ep-09-2020 19:29:16 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	aptured as ntermittent Lower ack Pain.
Sep-04-2020 07:41:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: NEW OR WORSENE D JOINT PAIN G2 is reported as Not Related to Study Treatment. Please add this event to the AE log. Else, clarify if captured under another AE entry
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 2 Event related to Study Treatment? NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Aug/19/2020

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)		(b) (4), (b) (6)	Symptom:: CHILLS Symptom Present:: NO	
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5.h Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	nitial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Aug-20-2020 17:23:35 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
ep-29-2020 12:27:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
ep-29-2020 12:27:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
ep-29-2020 12:27:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: ADVERSE EVENT	nitial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: 1	nitial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-13-2020 06:15:03 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Aug-12-2020 14:36:32 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	auto query (au oquery)	Query 1: Answered	ranscription Error
Aug-12-2020 14:36:32 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Redness at injection site	ranscription Error
Aug-12-2020 10:35:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	GPD Clin: REDNESS is reported as an AE. Please add more specific information to this event term for clarity.
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	D a Entry: Re ness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020 16:08	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)		(b) (4), (b) (6)	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/10/2020 17:08	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	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
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: N	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-11-2020 09:47:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Transcription Error

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED	nitial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	nitial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	nitial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 09:46:20 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
Aug-11-2020 09:46:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> N	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Swelling at injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020 16:08	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-18-2020 09:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-17-2020 18:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto query autoquery)	Query 1: Answered	Transcription Error
Aug-17-2020 18:48:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Transcription Error

090177e196ae40ca\Final\On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Aug/10/2020 17:08	
Aug-17-2020 15:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Please confirm that AE of Swelling at injection site with start date 10 Aug 2020 is still ongoing.
Aug-14-2020 18:15:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	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
Aug-14-2020 18:15:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: N	Initial Entry

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

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

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 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
Aug-14-2020 18:15:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	nitial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	nitial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> N	nitial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 18:15:56 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
Aug-14-2020 18:15:56 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> N	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: ADVERSE EVENT	nitial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: 3	nitial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lower Back Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/14/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-27-2020 17:13:05 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	H yley Wy r (b) (4)	Query 1: Closed	Response satisfies query
Aug-27-2020 09:40:47 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery	Query 1: Answered	New Information
Aug-27-2020 09:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	New Information

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Aug/17/2020 UNK:UNK	
Aug-27-2020 05:52:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Please review if AE 'Lower Back Pain' start 14Aug20 remains ongoing. Else, update with end date/time
Aug-26-2020 09:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	GPD Clin: Please review if AE 'Lower Back Pain' start 14Aug20 remains ongoing. Else, update with end date/time
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	nitial 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
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

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

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

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
ep-02-2020 12:58:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	H yley W per (b) (4)	Query 1: Closed	er site response
Aug-28-2020 11:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Intermittent Diarrhea, Chills and Lower Back Pain (12-14Aug20) have been reported to not be related to study treatment but UNKNOWN for other cause
Aug-28-2020 09:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Intermittent Diarrhea, Chills and Lower Back Pain (12-14Aug20) have been reported to not be related to study treatment but UNKNOWN for other cause. Please review if a probable cause can be ascertained for these events.
Aug-14-2020 18:18:23 (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: Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	D a Entry: N T APPLICABLE	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 09:41:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery	Query 1: Closed	Close Auto Query
Aug-27-2020 09:41:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	New Information
Aug-27-2020 09:40:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Lower Back Pain: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 18:18:23 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> N	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nausea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/10/2020 16:37	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/10/2020 17:08	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)

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

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
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	initial Entry

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

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

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> N	initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	initial Entry

12. Was a Non-Drug Treatment given?

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	nitial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 18:20:33 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

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Form Version: 22-Apr-2020 21:02

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Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-04-2020 06:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Cl osed	Response satisfies query
Sep-02-2020 12:21:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Cl osed	Response satisfies query
Sep-01-2020 18:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: A nswered	It can be confirmed this is the same reported occurrence.
Sep-01-2020 18:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: A nswered	Diarrhea did not meet COVID-19 surveillance, per PI.
Aug-31-2020 15:36:19 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: O p ned	GPD Clin: Intermittent diarrhea is recorded as

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)				ongoing since 12 Aug. Please confirm whether this adverse event meets protocol criteria for COVID-19 surveillance.
Aug-31-2020 12:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: O pened	e-Diary: AE 'Diarrhea' seems to be same as e-Diary Diarrhea Occurrence reported. Please reconcile or confirm in the query response as appropriate. Thanks
Aug-31-2020 07:55:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Cl osed	Response satisfies query
Aug-28-2020 11:06:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: A nswered	Transcription Error
Aug-28-2020 11:06:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Intermittent Diarrhea	Transcription Error
Aug-28-2020 02:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: O pened	Clarify INTERMITTANT DIARRHEA as follows. Please confirm if spelling should be INTERMITTENT DIARRHEA and edit term. Or further clarify and edit. Thank you.

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Aug-28-2020 01:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-27-2020 16:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-27-2020 16:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Intermittant Diarrhea	Transcription Error
Aug-27-2020 15:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify INTERMITTANT DIARRHEA as follows...Should the spelling be INTERMITTENT DIARRHEA? If so edit. Otherwise clarify. Thank you.
Aug-27-2020 09:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Intermittant Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 (UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/12/2020 UNK:UNK	nitial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
ep-10-2020 04:00:03 (UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	H ley Wyp (b) (4)	Query 2: Closed	Response satisfies query
Sep-09-2020 19:03:09	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Data is correct.

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Sep-04-2020 07:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Unplanned contact of 19Aug20 reports symptom of diarrhea present. Intermittent diarrhea in AE log is reported to end 19Aug20. Please confirm if data correct or any update to apply.
ep-02-2020 13:02:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	H ley Wyp (b) (4)	Query 1: Closed	Response satisfies uery
ep-01-2020 18:32:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	au query (a oquery)	Query 1: Answered	hanged Information
Sep-01-2020 18:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/19/2020 UNK:UNK	Changed Information
Aug-28-2020 05:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Event, INTERMITTENT DIARRHEA, starting 12Aug20 is reported to remain Ongoing. Please confirm if event now has an outcome and end date.
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	nitial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	nitial Entry

7. Is the adverse event serious?

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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	In tial Entry

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

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

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	In tial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
ep-02-2020 12:58:50 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	er site response
Aug-28-2020 11:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Intermittent Diarrhea, Chills and Lower Back Pain (12-14Aug20) have been reported to not be related to study treatment but UNKNOWN for other cause
Aug-28-2020 09:58:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Intermittent Diarrhea, Chills and Lower Back Pain (12-14Aug20) have been reported to not be related to study treatment but UNKNOWN for other cause. Please review if a probable cause can be ascertained for

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

				these events.
Aug-27-2020 09:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Transcription Error
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
ep-01-2020 18:34:16 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	auto query (au query)	Query 1: Closed	lose Auto Query
ep-01-2020 18:34:16 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Sep-01-2020 18:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Intermittent Diarrhea: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 09:44:20 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	In tial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: ADVERSE EVENT	nitial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	uto calc autocalc)	Data Entry: 6	nitial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
ep-04-2020 06:55:43 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
ep-01-2020 18:34:59 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is the same ccurrence.
Aug-28-2020 07:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	e-Diary: AE 'Chills' seems to be same as e-Diary Chills Occurrence reported. Please reconcile or confirm in the query response as appropriate. Thanks
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chills	nitial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/13/2020 UNK:UNK	In tial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

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Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time: Aug/14/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	In tial 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
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	In tial Entry

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

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

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	nitial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
ep-02-2020 12:58:59 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	per site response
Aug-28-2020 11:08:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ntermittent Diarrhea, hills and Lower ack Pain

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

				(12-14Aug20) have been reported to not be related to study treatment but UNKNOWN for other cause
Aug-28-2020 09:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Intermittent Diarrhea, Chills and Lower Back Pain (12-14Aug20) have been reported to not be related to study treatment but UNKNOWN for other cause. Please review if a probable cause can be ascertained for these events.
Aug-27-2020 09:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	In tial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 09:49:24 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	In tial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: ADVERSE EVENT	nitial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: 7	nitial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/8/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/28/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	initial Entry

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

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

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	initial Entry

12. Was a Non-Drug Treatment given?

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	nitial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 13:48:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (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: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
an-27-2021 13:31:11 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: Jan/25/2021	initial Entry

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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

Date	Location	User	Value	Reason
an-28-2021 11:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (toquery)	Query 1: Closed	Close Auto Query
Jan-27-2021 22:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-27-2021 13:31:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-27-2021 13:31:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
an-28-2021 11:33:27 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: Jan/25/2021	nitial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
an-28-2021 11:33:27 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
an-27-2021 13:32:01 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: Jan/26/2021	initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Jan-27-2021 13:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Jan/26/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
an-27-2021 13:32:49 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: Jan/26/2021	In tial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
an-27-2021 13:32:49 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: REPEAT SCREENING 1	nitial Entry

3. Status:

Date	Location	User	Value	Reason
an-27-2021 13:32:49 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: COMPLETED	In tial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
an-27-2021 13:33:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
an-27-2021 13:33:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
an-27-2021 13:33:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: Jan/26/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
an-27-2021 13:33:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
an-27-2021 13:33:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (o tocalc	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-27-2021 13:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Test::	Choriogonadotropin Beta_PX113
			Result::	
			Not Done::	NOT DONE

6.a Sponsor ID:

Date	Location	User	Value	Reason
an-27-2021 13:33:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
an-27-2021 13:33:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: horiogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
an-27-2021 13:33:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: NOT DONE	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
an-27-2021 13:35:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
an-27-2021 13:35:09 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: SERUM	nitial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
an-27-2021 13:36:42 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery	Query 1: Deleted	lose Auto Query
Jan-27-2021 13:35:09 (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.
Jan-27-2021 13:35:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: YES Date of Collection: Jan/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
an-27-2021 13:36:42 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie M ples (b) (4)	Data Entry: Sample ID: BR9R85	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

an-27-2021 13:36:42 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: BR9R85	Initial Entry
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5.b

Date	Location	User	Value	Reason
an-27-2021 13:37:10 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: Sample ID: BRT3W9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
an-27-2021 13:37:10 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: BRT3W9	Initial Entry

5.c

Date	Location	User	Value	Reason
an-27-2021 13:37:29 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: Sample ID: BRT3W8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
an-27-2021 13:37:29 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: BRT3W8	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
an-27-2021 13:38:06 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
an-27-2021 13:38:06 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: NASAL_SWAB	nitial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
an-27-2021 13:38:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery	Query 1: Deleted	lose Auto Query
Jan-27-2021 13:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-27-2021 13:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: YES Date of Collection: Jan/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
an-27-2021 13:38:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie M ples (b) (4)	Data Entry: Sample ID: BR9R8C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Jan-27-2021 13:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: BR9R8C	Initial Entry
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie M ples (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: INJECTION	nitial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie M ples (b) (4)	Data Entry: Jan/26/2021 10:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: DELTOID MUSCLE	nitial Entry

6. Body Side:

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: LEFT	nitial Entry

7. Route:

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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> INTRAMUSCULAR	nitial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> 30.0	nitial Entry

9. Unit:

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> 30 MINUTES	nitial Entry

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

Date	Location	User	Value	Reason
an-27-2021 13:39:22 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie M ples (b) (4)	<u>Data Entry:</u> YES	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
eb-16-2021 11:13:27 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: Feb/16/2021	nitial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
eb-16-2021 11:13:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
eb-16-2021 11:13:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
eb-16-2021 11:13:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: Feb/16/2021	nitial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
eb-16-2021 11:13:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
eb-16-2021 11:13:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: URINE	nitial Entry

6.a

Date	Location	User	Value	Reason
Feb-16-2021 11:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Test::	Choriogonadotropin Beta_PX113
			Result::	
			Not Done::	NOT DONE

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-16-2021 11:13:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-16-2021 11:13:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: horiogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-16-2021 11:13:37 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: NOT DONE	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
eb-16-2021 11:14:19 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
eb-16-2021 11:14:19 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: NASAL_SWAB	nitial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
eb-17-2021 09:14:49 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o query (toquery	Query 1: Closed	lose Auto Query
Feb-17-2021 08:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-16-2021 11:14:19 (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-16-2021 11:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Data Entry: YES Date of Collection: Feb/16/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-17-2021 09:14:49 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Mollie Maples	Data Entry: Sample ID: BR9RCN	Initial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1080

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject No: 10801006

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)

(b) (4)

5.a Sample ID

Date	Location	User	Value	Reason
eb-17-2021 09:14:49 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	<u>Data Entry:</u> BR9RCN	initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie M ples (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a calc (au ocalc	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: INJECTION	nitial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie M ples (b) (4)	Data Entry: Feb/16/2021 09:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	Data Entry: DELTOID MUSCLE	nitial Entry

6. Body Side:

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	M llie M ples (b) (4)	Data Entry: RIGHT	nitial Entry

7. Route:

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090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> INTRAMUSCULAR	nitial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> 30.0	nitial Entry

9. Unit:

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (tocalc	<u>Data Entry:</u> 30 MINUTES	nitial Entry

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

Date	Location	User	Value	Reason
eb-16-2021 11:14:55 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	Mollie M ples (b) (4)	<u>Data Entry:</u> YES	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
ep-29-2020 12:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc (autocalc)	Data Entry: FOLLOW-UP	nitial Entry
Aug-11-2020 08:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	uto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	nitial Entry
Aug-10-2020 18:20:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	a calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
eb-15-2021 03:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	rroneous entry
eb-12-2021 08:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	M llie Map (b) (4)	Query 1: Answered	Yes, erroneous.
Feb-12-2021 01:26:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Response states "Patient answered "yes" in diary but symptoms were not aligned with COVID-19". Please confirm if Illness ediary entry of 08FEB2021 was deemed erroneous.
Feb-11-2021 14:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mollie Maples (b) (4)	Query 1: Answered	Patient answered "yes" in diary but symptoms were not aligned with COVID-19 list of symptoms.
Feb-11-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

		(b) (4), (b) (6)		"Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 08FEB2021. But there is no COVID Illness visit reported in the database. Please clarify.
ep-29-2020 12:27:46 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (o calc)	Data Entry: Sep/28/2020	nitial Entry
Aug-11-2020 08:31:49 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (o calc)	Data Entry: Aug/10/2020	nitial Entry
Aug-10-2020 18:20:02 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	a o calc (o calc)	Data Entry: Aug/10/2020	nitial Entry

090177e196ae40ca\Final\Final On: 01-Apr-2021 05:43 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801006

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
ep-14-2020 09:29:18 UTC-05:00) Eastern Time US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	nitial Entry