

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1080

Subject No: 10801013

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

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/11/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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/11/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1080

Subject No: 10801013

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 |
|----|---|----------------|

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: 10801013
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/11/2020 |
| 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: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|-----------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Fibromyalgia] |
| | Start Date: | UNK/UNK/1990 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hypertension] |
| | Start Date: | UNK/UNK/1995 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Dry Eyes, Bilateral] |
| | Start Date: | UNK/UNK/2019 |
| | Ongoing: | YES |
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Insomnia] |
| | Start Date: | UNK/UNK/2012 |
| | Ongoing: | YES |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

| | | |
|-----|--|---------------------------------|
| 1.e | Line/MH Number: | [5] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Upset Stomach] |
| | Start Date: | UNK/UNK/2012 |
| | Ongoing: | YES |
| 1.f | Line/MH Number: | [6] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Dermatographia] |
| | Start Date: | UNK/UNK/2018 |
| | Ongoing: | YES |
| 1.g | Line/MH Number: | [7] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Torn Meniscus] |
| | Start Date: | UNK/UNK/2005 |
| | Ongoing: | NO End Date: UNK/UNK/2005 |
| 1.h | Line/MH Number: | [8] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Bilateral Inguinal Hernia] |
| | Start Date: | Jul/UNK/2006 |
| | Ongoing: | YES |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL 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

| | | |
|-----|--|---------------------------------|
| 1.i | Line/MH Number: | [9] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Knee Replacement, Left Leg] |
| | Start Date: | Jan/UNK/2011 |
| | Ongoing: | NO End Date: Jan/UNK/2011 |
| 1.j | Line/MH Number: | [10] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Osteoarthritis] |
| | Start Date: | UNK/UNK/2020 |
| | Ongoing: | YES |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1080

Subject No: 10801013

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/11/2020 |
| 2. | Weight: | [66.5] |
| 3. | Unit: | kg |
| 4. | Height: | [156.5] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [27.2] |

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801013

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/11/2020 |
| 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 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/11/2020 |
| 2. | Randomization Number: | [225859] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/11/2020 |
| 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 | [BP59VY] |
| 5.b | Sample ID | [BP59VZ] |
| 5.c | Sample ID | [BP59W0] |
| 5.d | Sample ID | [BPRN5X] |
| 5.e | Sample ID | [BPRN5Y] |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/11/2020 |
| 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 | [BP59FW] |
|-----|-----------|----------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

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/11/2020 13:42 |
| 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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1080

Subject No: 10801013

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 |
|----|---|---|

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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 | Sep/1/2020 |
| 2. | Erroneous Visit | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

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? | NO |
| 2.a | Symptom: | FEVER |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.b | Symptom: | FATIGUE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | YES Ongoing? NO Stop Date: Sep/1/2020 |
| 2.c | Symptom: | HEADACHE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

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? | NO |
| 2.h | Symptom: | NEW OR WORSENERED JOINT PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 3. | Injection Site Location: | DELTOID MUSCLE |
| 4. | Injection Site Body Side: | LEFT |
| 5.a | Injection Site Reaction: | REDNESS |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.b | Injection Site Reaction: | SWELLING |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.c | Injection Site Reaction: | PAIN AT INJECTION SITE |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1080

Subject No: 10801013

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: | Sep/1/2020 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [98.4] |
| | 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: 10801013

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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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: Sep/1/2020 |
| 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 | [BP59LF] |
|-----|-----------|----------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

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: | Sep/1/2020 12:20 |
| 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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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 | Sep/30/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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 Symptoms Diary - Symptom Resolved Dates

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

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

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

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/30/2020 |
| 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 | [BPTSPS] |
|-----|-----------|----------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1080

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

Subject No: 10801013

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 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

| | | |
|----|----------------------|--|
| 4. | Symptoms: | |
| | Was symptom present? | |

Symptoms - Other

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

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1080

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

Subject No: 10801013

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: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1080

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

Subject No: 10801013

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 | [] |
|----|-----------|-----|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

| | | |
|----|--|--|
| 1. | Category of Clinical Event: | |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | |
| 3. | Toxicity Grade: | |

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT

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 | |

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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 | [] |
|----|-----------|-----|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1080

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

Subject No: 10801013

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 - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

| | | |
|----|-------------|--|
| 1. | Assessments | |
|----|-------------|--|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1080

Subject No: 10801013

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/30/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1080

Subject No: 10801013

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: 10801013

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: | |
|----|-----------------------|--|

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: 10801013

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 | [] |
|----|-----------|-----|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

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: 10801013

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 Ongoing | Form Instance |
|----|---------------|---------------|----------------------------|-------------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Osteoarthritis of the knee | Oct/26/2020 UNK: UNK | NO End Date Time: Oct/26/2020 UNK:UNK | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | Perforated Colon | Oct/31/2020 UNK: UNK | YES | Repeating Pages |
| 3. | ADVERSE EVENT | 3 | Ischemic colitis | Oct/31/2020 UNK: UNK | YES | Repeating Pages |
| 4. | ADVERSE EVENT | 4 | Constipation | Oct/31/2020 UNK: UNK | YES | Repeating Pages |
| 5. | ADVERSE EVENT | 5 | Atrial Fibrillation | Nov/11/2020 UNK: UNK | YES | Repeating Pages |
| 6. | ADVERSE EVENT | 6 | Diuresis | Nov/9/2020 UNK: UNK | YES | Repeating Pages |
| 7. | ADVERSE EVENT | 7 | Acute parotitis | Nov/8/2020 UNK: UNK | YES | Repeating Pages |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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Adverse Event Report

| | | |
|----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Osteoarthritis of the knee] |
| 4. | Start Date Time: | Oct/26/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Oct/26/2020 UNK:UNK |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

| | | |
|-----|--|---|
| 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: [Osteoarthritis of the knee which led to knee replacement] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020443255] |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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Adverse Event Report

| | | |
|----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Perforated Colon] |
| 4. | Start Date Time: | Oct/31/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Constipation] | Comments |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE | |
| 11. | Was a Concomitant Medication given? | YES | |
| 12. | Was a Non-Drug Treatment given? | YES | |
| 13. | What was the outcome of this adverse event?: | RECOVERING/RESOLVING | |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO | |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020443355] | |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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Adverse Event Report

| | | |
|----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [3] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Ischemic colitis] |
| 4. | Start Date Time: | Oct/31/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES |
| 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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Constipation] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020443355] |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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Adverse Event Report

| | | |
|----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [4] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Constipation] |
| 4. | Start Date Time: | Oct/31/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES |
| 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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1080
Subject No: 10801013
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete
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: | 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? | YES |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020443355] |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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Adverse Event Report

| | | |
|-----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [5] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Atrial Fibrillation] |
| 4. | Start Date Time: | Nov/11/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | 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 |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

| | | |
|-----|--|----------------------------|
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | NOT RECOVERED/NOT 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 | [] |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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Adverse Event Report

| | | |
|-----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [6] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Diuresis] |
| 4. | Start Date Time: | Nov/9/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | 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 |

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Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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Subject Initials: ---

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| | | |
|-----|--|----------------------------|
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | NOT RECOVERED/NOT 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 | [] |

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Adverse Event Report

| | | |
|-----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [7] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Acute parotitis] |
| 4. | Start Date Time: | Nov/8/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | 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 |

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Site No: 1080
Subject No: 10801013
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete
Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1080

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

Subject No: 10801013

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 |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1080

Subject No: 10801013

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

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Medication Error

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

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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: 10801013

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. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 2. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 3. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 4. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 5. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 6. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 7. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 8. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 9. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 10. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| 11. DELETED | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

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Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

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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: 10801013

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 | Dose Description | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

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Site No: 1080

Subject No: 10801013

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: ---

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Concomitant Medications

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

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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: 10801013

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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1080
Subject No: 10801013
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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

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: 10801013

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: | |

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: 10801013

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: | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

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: | |
| 6. | Body Side: | |
| 7. | Route: | |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

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: 10801013

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: 10801013

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/5/2021 |
| 2. | Erroneous Visit | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

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](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/5/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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 : | // |
|----|------------------------------|----|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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

| | | |
|----|------------------------|-----|
| 2. | 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: 10801013

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/14/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1080

Subject No: 10801013

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

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Jan/14/2021 |
|----|--------------|--|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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 |
|----|---|----------------|

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1080

Subject No: 10801013

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/14/2021 |
| 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: 10801013
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/14/2021 |
| 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 |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/14/2021 |
| 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 | [BPTSCX] |
| 5.b | Sample ID | [BRT3TN] |
| 5.c | Sample ID | [BRT3TR] |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/14/2021 |
| 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 | [BPTS5N] |
|-----|-----------|----------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801013

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/14/2021 13:26 |
| 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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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/4/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1080

Subject No: 10801013

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/4/2021 |
| 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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/4/2021 |
| 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 | [BR9R9M] |
|-----|-----------|----------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801013

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/4/2021 12:10 |
| 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 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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 | Mar/4/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001
Visit: V103_MONTH1
Form Version: 22-Apr-2020 21:04
Site No: 1080
Subject No: 10801013
Generated By: (b) (4)

Form: CONTACT OUTCOME
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](#)

Contact Outcome

| | | |
|----|-------------------|---------------------------------------|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Mar/4/2021 |
| 3. | Comments: | [] |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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: 10801013

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: 10801013

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: 10801013

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: Data Complete, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|--|----------------------|
| 1. | Date of Completion/Discontinuation /Death : | Mar/4/2021 |
| 2. | Phase of Disposition: | OPEN LABEL TREATMENT |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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/30/2020 |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

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 |
|----|--------------------|----------------------|

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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: 10801013
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: ---
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| Item | Date | User | Comment |
|------|---|------------------|------------------|
| Form | Aug-11-2020 18:26:32 (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: 10801013

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: ---

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| Item | Date | User | Comment |
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| Form | Sep-03-2020 15:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1080

Subject No: 10801013

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

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| Item | Date | User | Comment |
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| 1 | Sep-03-2020 15:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

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Site No: 1080

Subject No: 10801013

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

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| Item | Date | User | Comment |
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| 2 | Sep-03-2020 15:28:27 (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: 10801013

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Sep-03-2020 15:28:27 (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: 10801013

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 4 | Sep-03-2020 15:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L
Form Version: 30-Jul-2020 21:27
Site No: 1080
Subject No: 10801013
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: ---
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| Item | Date | User | Comment |
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| 5 | Sep-03-2020 15:28:27 (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: 10801013

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: ---

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 6.a | Sep-03-2020 15:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L
Form Version: 30-Jul-2020 21:27
Site No: 1080
Subject No: 10801013
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
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| Item | Date | User | Comment |
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| 6.a | Sep-03-2020 15:28:27 (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: 10801013

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: ---

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 6.a | Sep-03-2020 15:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

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

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 9 | Nov-13-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | A confirmed possible etiology will be entered once the patient is out of the hospital and medical records have been received. |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

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Generated By: (b) (4)

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| Item | Date | User | Comment |
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| Form | Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

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Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 2 | Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 3 | Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 4 | Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

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Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

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| 5 | Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Form Status: Data Complete, Deleted, Verified

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

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| Form | Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Deleted, Verified

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| Item | Date | User | Comment |
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| 2 | Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

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| 3 | Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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| Item | Date | User | Comment |
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| 4 | Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Form Status: Data Complete, Deleted, Verified

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| Item | Date | User | Comment |
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| 5 | Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

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| Item | Date | User | Comment |
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| Form | Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Site No: 1080

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| Item | Date | User | Comment |
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| 2 | Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Status: Data Complete, Deleted, Verified

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| Item | Date | User | Comment |
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| 3 | Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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| Item | Date | User | Comment |
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| 4 | Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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| 5 | Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Status: Data Complete, Deleted, Verified

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Generated By: (b) (4)

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| Item | Date | User | Comment |
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| Form | Aug-12-2020 13:00:57 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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

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| 1 | Aug-12-2020 13:00:57 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Form Status: Data Complete, Deleted, Verified

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

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| 2 | Aug-12-2020 13:00:57 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

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Site No: 1080

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| 1 | Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2 | Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 4 | Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5 | Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2 | Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 4 | Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5 | Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

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

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| Item | Date | User | Comment |
|------|--|--------------------------|----------------|
| Form | Jan-21-2021 14:47:18 (UTC-05:00) Eastern Time (US & Canada) | Mollie Maples (b) (4) | Not Applicable |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign
- CRF_Sign_1

| Name | Signature Meaning | Date | Type | Action |
|---------------|-------------------|---|------|-----------------------------------|
| Mollie Maples | N/A | Feb-04-2021 13:03:09 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |

Affidavit:
N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Sylvia Shoffner | Approved | Jan-21-2021 16:32:40 (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 | Nov-20-2020 11:21:10 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:
N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Sylvia Shoffner | Approved | Nov-16-2020 17:36:12 (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.

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Sylvia Shoffner | Approved | Oct-12-2020 12:51:05 (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 | Sep-30-2020 17:04:49 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Sylvia Shoffner | Approved | Sep-18-2020 17:02:58 (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.

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1080

Subject No: 10801013

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

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 17:48:53 (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-11-2020 17:48:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-11-2020 17:49:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Aug/11/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1080

Subject No: 10801013

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

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Aug-11-2020 17:48:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10801013 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Aug-11-2020 17:48:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1942 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-11-2020 17:49:24 (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-11-2020 17:49:24 (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-11-2020 17:49:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 17:49:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 17:49:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-11-2020 17:49:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Aug-11-2020 17:49:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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I.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-11-2020 17:50:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Te Fibromyalgia rm: Start Date: UNK/UNK/1 990 Ongoing: YES | Initial Entry |

I.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 17:50:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------|-------------------|--|
| Aug-13-2020 06:30:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Closed | Response satisfies query |
| Aug-12-2020 16:30:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Condition is Stable |
| Aug-12-2020 14:01:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Opened | GPD Clin: Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of symptoms within 6 weeks of enrolment and no acute event within 48h before study intervention administration |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

| | | | | |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 17:50:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Fibromyalgia | Initial Entry |
|---|-----------------|---------------------|------------------------------------|---------------|

I.a Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 17:50:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1990 | Initial Entry |

I.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 17:50:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-11-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 2 Medical History Te Hypertension rm: Start Date: UNK/UNK/1 995 Ongoing: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Hypertension | Initial Entry |

1.b Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1995 | Initial Entry |

1.b Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 17:51:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-11-2020 17:52:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 3 : Medical History T Dry Eyes, Bilateral Start Date: UNK/UNK/2019 Ongoing: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 17:52:28 (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-11-2020 17:52:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dry Eyes, Bilateral | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 17:52:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2019 | Initial Entry |

I.c Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 17:52:28 (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-11-2020 18:05:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 4 Medical History Te Insomnia rm: Start Date: UNK/UNK/2 012 Ongoing: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.d Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 18:05:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Aug-11-2020 18:05:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Insomnia | Initial Entry |

I.d Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 18:05:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2012 | Initial Entry |

I.d Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 18:05:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.e

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-11-2020 18:06:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 5 Medical History Te Upset Stomac rm: h Start Date: UNK/UNK/2 012 Ongoing: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.e Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 18:06:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 5 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------------|---------------|
| Aug-11-2020 18:06:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Upset Stomach | Initial Entry |

I.e Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 18:06:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2012 | Initial Entry |

I.e Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 18:06:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-11-2020 18:06:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 6 Medical History Te Dermatograph rm: ia Start Date: UNK/UNK/2 018 Ongoing: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.f Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 18:06:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Aug-11-2020 18:06:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dermatographia | Initial Entry |

I.f Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 18:06:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2018 | Initial Entry |

I.f Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 18:06:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-11-2020 18:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 7 Medical History Term: Torn Meniscus Start Date: UNK/UNK/2005 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

| | | | | | |
|--|--|--|-----------------|------------------|--|
| | | | Ongoing: | NO | |
| | | | | End Date: | |
| | | | | UNK/UNK/ 2005 | |

I.g Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 18:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------------|---------------|
| Aug-11-2020 18:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Torn Meniscus | Initial Entry |

I.g Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 18:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2005 | Initial Entry |

I.g Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 18:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/2005 | Initial Entry |

I.h

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-11-2020 18:08:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 8 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

| | | | | |
|--|--|--|--|--|
| | | | Medical History Bilateral Inguinal Term: Hernia Start Date: Jul/UNK/2006 Ongoing: YES | |
|--|--|--|--|--|

1.h Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 18:08:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 8 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 18:08:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bilateral Inguinal Hernia | Initial Entry |

1.h Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 18:08:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jul/UNK/2006 | Initial Entry |

1.h Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 18:08:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.i

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-11-2020 18:09:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Nu 9 mber: Medical Histo Knee Replacement ry Term: , Left Leg Start Date: Jan/UNK/2011 | Initial Entry |

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Header Text: c4591001

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Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

| | | | | |
|--|--|--|--------------------|--|
| | | | Ongoing: NO | |
| | | | End Date: | |
| | | | Jan/UNK/2011 | |

1.i Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-11-2020 18:09:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 9 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------|---|
| Nov-21-2020 16:16:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Nov-20-2020 15:29:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Completed as requested |
| Nov-19-2020 14:32:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | Clinical - SAE medical history now includes the underlying condition of OA; however, it does not appear on the Med Hx CRF. Please review for clinical relevance to safety event and update Med Hx log CRF if appropriate. |
| Nov-16-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-16-2020 14:19:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---|
| Nov-16-2020 13:30:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Site does not have OA reported on the patient's medical history. Will update once medical records are received documenting a medical history if OA. |
| Nov-16-2020 13:26:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Clinical - Please note that OA is already reported on the SAE report; please harmonize the reporting of this condition by also documenting OA on the Med Hx CRF |
| Nov-16-2020 12:59:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Will update once medical records are recieved and more information is available. |
| Nov-16-2020 12:58:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Will update once medical records are recieved and more information is available. |
| Nov-14-2020 18:06:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | CLINICAL - Subject has past Med Hx of Left TKR. Please clarify if SAE (#202043255) is now Right TKR, or revision of Left TKR, and update with a SAE safety |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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: ---

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| | | | | |
|---|-----------------|---------------------|--|---|
| | | | | update |
| Nov-14-2020 18:05:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINICAL - Subject has SAE for TKR for the condition Osteoarthritis of the knee; however, Med history on CRF and SAE do not include this condition. Meniscal tear is documented. Please clarify condition and update Med Hx CRF, and SAE if required. |
| Aug-11-2020 18:09:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Knee Replacement, Left Leg | Initial Entry |

1.i Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-11-2020 18:09:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/UNK/2011 | Initial Entry |

1.i Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 18:09:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Jan/UNK/2011 | Initial Entry |

1.j

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------------|
| Nov-23-2020 09:13:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number 10 : | Transcription Error |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

| | | | | |
|---|-----------------|----------------------|---|---------------|
| | | | Medical History Term: Osteoarthritis Start Date: UNK/UNK/2020 Ongoing: YES | |
| Nov-20-2020 15:27:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 10 Medical History Term: Osteoarthritis Start Date: UNK/UNK/2020 Ongoing: NO End Date: Oct/26/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.j Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Nov-20-2020 15:27:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 15:27:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Osteoarthritis | Initial Entry |

1.j Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------|--|
| Dec-06-2020 11:43:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Acceptable response |
| Dec-02-2020 16:31:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | We do not have a start date for OA. It was prior to study, but we are not sure when it actually began. |
| Dec-01-2020 19:29:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | CLINICAL Start date of medical history of OA would precede the first (Lt) total knee replacement in 2011, if subject's Med Hx is that TKR was also for OA. Start date of Med Hx cannot be after Day 1 (it would be AE) |
| Nov-22-2020 23:20:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

| | | | | |
|---|-----------------|---------------------------|------------------------------------|--|
| Nov-20-2020 15:28:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | The start date is unknown. |
| Nov-20-2020 15:27:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Start Date is after or equal to the first vaccination date 11/Aug/2020. Please review and update as appropriate. |
| Nov-20-2020 15:27:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

Lj Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------|--|--|
| Nov-23-2020 09:53:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-23-2020 09:13:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-23-2020 09:13:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Transcription Error |
| Nov-23-2020 08:10:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Opened | CLINQUERY: If the knee replacement reported within the AE listing was not a planned procedure from MH, then please leave this event of OA ongoing at V1. Else, clarify |
| Nov-20-2020 15:27:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Oct/26/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1080

Subject No: 10801013

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

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Aug/11/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 66.5 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 156.5 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 27.2 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1080

Subject No: 10801013

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

| | | | | |
|--------------------|--|--|--|--|
| Time (US & Canada) | | | | |
|--------------------|--|--|--|--|

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 97.6 Temperature Unit: F Temperature Location: FOREHEAD | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Aug-11-2020 18:11:54 (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-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.6 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Aug-11-2020 18:11:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject No:** 10801013**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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 06:42:10 (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. |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|---------------------|--------------------------------|---------------|
| Aug-11-2020 18:14:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 18:15:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-11-2020 18:15:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 225859 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-11-2020 18:15:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-11-2020 18:15:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--|
| Aug-13-2020 08:13:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Aug-13-2020 07:57:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM Query: Response for 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. Thank you. |
| Aug-11-2020 18:15:16 (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-11-2020 18:15:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|-------------|--|
| | | | Aug/11/2020 | |
|--|--|--|-------------|--|

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-13-2020 08:13:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP59VY | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-13-2020 08:13:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP59VY | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-13-2020 08:13:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP59VZ | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-13-2020 08:13:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP59VZ | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-13-2020 08:13:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP59W0 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-13-2020 08:13:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP59W0 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------------|
| Aug-13-2020 08:14:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPRN5X | Transcription Error |
| Aug-13-2020 08:14:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPRN5X | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|------------------------------|---|
| Aug-13-2020 08:14:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Aug-13-2020 08:14:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Aug-13-2020 08:14:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPRN5X | Transcription Error |
| Aug-13-2020 08:14:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys. |
| Aug-13-2020 08:14:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Barcode is not 6 characters in length. Please review and correct as appropriate. |
| Aug-13-2020 08:14:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPRN5X | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-13-2020 08:15:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPRN5Y | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-13-2020 08:15:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPRN5Y | Initial Entry |

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject No:** 10801013**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-11-2020 18:15:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-11-2020 18:15:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Aug-11-2020 18:25:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-11-2020 18:15:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-11-2020 18:15:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/11/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 18:25:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP59FW | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-11-2020 18:25:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BP59FW | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

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

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-11-2020 18:16:25 (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-11-2020 18:16:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-11-2020 18:16:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 18:16:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 13:42 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-11-2020 18:16:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Aug-11-2020 18:16:25 (UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

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

| | |
|--------------------|------------------|
| Time (US & Canada) | (b) (4), (b) (6) |
|--------------------|------------------|

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-11-2020 18:16:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-11-2020 18:16:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 18:16:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1080

Subject No: 10801013

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

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 18:16:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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 |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-03-2020 15:27:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 | 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:** 10801013**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the last O day the Subject Diary was completed?: | Initial Entry |

2.a Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-11-2020 12:07:19 (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-11-2020 12:07:19 (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-17-2020 09:42:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FATIGU E | 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: 10801013

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?</p> <p>NO</p> <p>Stop Date:</p> <p>Se p/1 /20 20</p> | |
| Sep-15-2020 17:02:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>Symptom:: FA TI GU E</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> | Transcription Error |
| Sep-15-2020 16:55:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>Symptom:: FATIGUE</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>UN K/U NK/ 202 0</p> | Transcription Error |
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>Symptom:: FA TI</p> | 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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> FATIGUE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|--|
| Sep-18-2020 04:33:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Sep-17-2020 09:42:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Sep-17-2020 09:42:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES Ongoing? NO Stop Date: Sep/1/2020 | Initial Entry |
| Sep-16-2020 10:15:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM 2: Thanks for your response. Please verify and update data for Fatigue as it is reported on Last day (Day 7) in e-diary. Thank you. |
| Sep-15-2020 17:02:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Transcription Error |
| Sep-15-2020 16:55:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:11

| | | | | |
|--|-----------------|------------------|---|--|
| Sep-15-2020 16:55:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Ongoing? NO Stop Date: UNK/UNK/2020 | Transcription Error |
| Sep-15-2020 03:12:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM 1: Please verify and update data for Fatigue as it is reported on Last day (Day 7) in e-diary. Thank you. |
| Sep-14-2020 17:27:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |
| Sep-14-2020 01:26:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | e-Diary: Per eDiary records, FATIGUE is reported on Last day however the last day in inform is entered as 'No' for the same. Please verify and update. Else, clarify. Thanks |
| Sep-11-2020 12:07:19 (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-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: HE AD AC HE | 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: 10801013

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?: | |
|--|--|--|---|--|

2.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------|---------------|
| Sep-11-2020 12:07:19 (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-11-2020 12:07:19 (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-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> CHILLS | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> VO MIT ING <u>Were fever or systemic sy NO</u> <u>mptoms present on the la</u> <u>st day the Subject Diary</u> <u>was completed?:</u> | Initial Entry |

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.f

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?: | Initial Entry |

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-11-2020 12:07:19 (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-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?: | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENER MUSCLE PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.h

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSENER JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENER JOINT PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Sep-11-2020 12:07:19 (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-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.b

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?: | Initial Entry |

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-11-2020 12:07:19 (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-11-2020 12:07:19 (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-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reactio PAIN A n:: T INJE CTION SITE Were injection site rea NO ctions present on the l ast day the Subject Di ary was completed?: | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-11-2020 12:07:19 (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-11-2020 12:07:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1080

Subject No: 10801013

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 |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-03-2020 15:27:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-03-2020 15:27:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 98.4 Temperature Unit: F Temperature Locat ORAL CAVI ion:: TY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-03-2020 15:27:49 (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 |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-03-2020 15:27:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 98.4 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-03-2020 15:27:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

2.a Temperature Location:

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1080

Subject No: 10801013

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:27:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject No:** 10801013**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|---|-----------------|---------------------|---|--|---------------|
| Sep-03-2020 15:28:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done:: | Not Applic able Not Applic able Not Applic able Not Applic able | Initial Entry |
|---|-----------------|---------------------|---|--|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:28:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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:** 10801013**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 |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-03-2020 15:29:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-03-2020 15:29:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Sep-03-2020 15:29:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-03-2020 15:29:17 (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-03-2020 15:29:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/1/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-03-2020 15:29:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP59LF | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 15:29:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP59LF | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

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

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 12:20 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

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

| | |
|--------------------|------------------|
| Time (US & Canada) | (b) (4), (b) (6) |
|--------------------|------------------|

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:30:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|--|
| Nov-11-2020 06:39:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | event recorded in PDB |
| Nov-11-2020 06:39:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | event recorded in PDB |
| Nov-11-2020 01:30:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Reissued:Candidat e | Response does not satisfy query |
| Nov-11-2020 01:30:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued:Candidat e | Response does not satisfy query |
| Nov-10-2020 12:16:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Answered | This SAE has been entered |
| Nov-10-2020 12:16:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | This SAE has been entered |
| Nov-10-2020 08:21:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | SAE RECON:AER#2020443255 BOWEL PROBLEMS(onset date:31Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Nov-10-2020 08:20:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | SAE RECON:AER#2020443255 Osteoarthritis(onset date:26Oct2020)was reported as serious in Safety database but missing |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

| | | | | |
|--|-----------------|---------------------|-----------------------------------|--|
| | | | | in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Oct-08-2020 05:45:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Oct-08-2020 02:56:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-07-2020 15:29:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |
| Oct-07-2020 15:29:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per subject report should be considered a mistake. |
| Oct-07-2020 05:42:07 (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. |
| Oct-03-2020 04:45:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 11SEP2020. But there is no COVID Illness visit reported in the database. Please clarify. |
| Sep-30-2020 17:04:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/30/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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:** 10801013**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the last O day the Subject Diary was completed?: | Initial Entry |

2.a Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Oct-07-2020 15:22:27 (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-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FA TI | 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: 10801013
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:11

| | | | | |
|--|--|--|---------------|--|
| | | | GU E NO | |
| Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | | | | |

2.b Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Oct-07-2020 15:22:27 (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 15:22:27 (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-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

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 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.d Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> CHILLS | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.e

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: VO MIT ING Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?: | Initial Entry |

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-07-2020 15:22:27 (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 15:22:27 (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 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?: | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> DIARRHEA | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW OR WORSE MUSCLE PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

2.h

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?: | Initial Entry |

2.h Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSE NED JOI NT PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-07-2020 15:22:27 (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 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactio ns present on the last day the Subject Diary was co mpleted?: NO | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Oct-07-2020 15:22:27 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-07-2020 15:22:27 (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 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti ons present on the last da y the Subject Diary was c ompleted?: NO | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> SWELLING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> PAIN AT INJECTION SITE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-07-2020 15:22:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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:** 10801013**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 |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-30-2020 17:05:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-30-2020 17:05:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Oct-01-2020 07:26:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Oct-01-2020 05:09:44 (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-30-2020 17:05:03 (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-30-2020 17:05:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/30/2020 | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-01-2020 07:26:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPTSPS | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-01-2020 07:26:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPTSPS | Initial Entry |

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1080

Subject No: 10801013

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

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-30-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/30/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-30-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Sep-30-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-10-2020 12:10:35 (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: 10801013

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-20-2020 11:24:53 (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: 10801013

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-20-2020 16:30:00 (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: 10801013

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-20-2020 16:31:09 (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: 10801013

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-20-2020 16:31:57 (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: 10801013

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

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|--------------------------------------|--|
| Nov-14-2020 13:02:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Nov-11-2020 21:43:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Query closed; will follow for SAE update with the requested TKR info |
| Nov-11-2020 10:46:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | Changed Information |
| Nov-11-2020 10:46:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Osteoarthritis | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

| | | | | |
|--|---|--------------------------|------------------------------|--|
| Canada) | | | is of t he kn ee | |
| Nov-11-2020 08:05:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Clo sed | issued another query |
| Nov-11-2020 08:05:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Op ened | Please only retain the diagnosis that led to the surgical procedure by amending the term to "osteoarthritis of the knee." |
| Nov-10-2020 15:55:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 2: Op ened | Multiple concepts in the term OSTEOARTHRITIS OF THE KNEE WHICH LED TO KNEE REPLACEMENT. Split the term into OSTEOARTHRITIS OF THE KNEE and KNEE REPLACEMENT and report as separate entries. Thank you. |
| Nov-10-2020 15:22:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: An swere d | This is unknown. We talked to the patient's husband since patient is currently hospitalized. |
| Nov-10-2020 13:31:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Op ened | Clinical - please specify here and in SAE which side received the TKR. |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

| | | | | |
|--|-----------------|------------------|---|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: : Osteo arthrit is of t he kn ee wh ich le d to k nee re place ment | Initial Entry |
|--|-----------------|------------------|---|---------------|

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/26/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Oct/26/2020 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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 |
|---|-----------------|---------------------------|---|--|
| Nov-11-2020 21:45:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Query closed; will follow for SAE update with the requested COVID test info |
| Nov-11-2020 01:10:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-10-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | We do not have this information as we have not received medical records yet. A request has been sent. |
| Nov-10-2020 13:32:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical COVID test status (yes/no) during Hosp was not reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020443255] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date |
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Osteoarthritis of the knee which led to knee replacement: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birt | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

| | | | | |
|--|--|--|---|--|
| | | | h defect? | |
| | | | NO | |
| | | | Did this serious event result in death? | |
| | | | NO | |
| | | | Did this serious event require or prolong hospitalization? | |
| | | | YES | |
| | | | Did this serious event result in persistent or significant disability/incapacity? | |
| | | | NO | |
| | | | Is this serious event life threatening? | |
| | | | NO | |
| | | | Other medically important serious event | |
| | | | NO | |

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

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-10-2020 12:10:35 (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 |
|--|-----------------|-------------------------|-----------------|---|
| Nov-13-2020 12:20:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Closed | To review at later date if records obtained |

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1080

Subject No: 10801013

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

| | | | | |
|---|-----------------|----------------------------|--|--|
| Nov-11-2020 17:28:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | at this point it is unknown as to whether the osteoarthritis should be entered into the medical history. Once the medical records have been received for this event more evaluation can occur. |
| Nov-11-2020 16:48:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Opened | CLINQUERY: Please note, a prior knee replacement is captured in MH but no entry for osteoarthritis. Please review if the MH should capture an OA entry if this condition was present prior to the study (pg can be unlocked for update) |
| Nov-10-2020 12:10:35 (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> Osteoarthritis of the knee which led to knee replacement | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10801013

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: ---

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11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-10-2020 12:10:35 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-10-2020 12:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Nov-11-2020 01:10:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 2020443255 | Initial Entry |

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Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---|
| Nov-23-2020 20:42:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Closed | Response satisfies query |
| Nov-23-2020 20:42:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Closed | Response satisfies query |
| Nov-23-2020 15:05:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Answered | Medical records do not mention a cause for the constipation. The constipation is the reason the patient went to the hospital. |
| Nov-23-2020 15:03:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Answered | Parotitis is inflammation of the parotid gland. Medical records just stated that this is what led to performing a exploratory laparotomy. |
| Nov-21-2020 16:14:43 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Reissued:Opened | CLINICAL As the |

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Subject No: 10801013

Generated By: (b) (4)

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Form Status: Data Complete

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| | | | | |
|---|-----------------|------------------------|--|---|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | event CONSTIPATION was the etiology for the other SAEs, and if not attributed to post-op narcotics, please submit a safety F/U for the evaluation of the SAE Constipation and it's cause |
| Nov-21-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Nov-21-2020 16:12:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | Response satisfies query |
| Nov-21-2020 16:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Reissued:Opened | CLINICAL - please clarify if reporting acute inflammatory process of the parotid gland(s) with 'parotitis'; and how this event would be evaluated by exp laparotomy. |
| Nov-20-2020 11:21:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Answered | New Information |
| Nov-20-2020 11:21:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | New Information |
| Nov-20-2020 11:21:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Perforated Colon | New Information |
| Nov-20-2020 11:16:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Answered | Medical records do not mention anything in regards to the duration of pain medication given for TKR. Per medical records, no bowel |

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Header Text: c4591001

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|---|-----------------|---------------------|-------------------|---|
| | | | | regimen was prescribed. |
| Nov-20-2020 09:18:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Answered | According to the medical records, when the patient developed acute parotitis, the doctors decided to perform an exploratory laparotomy which led to the diagnosis of perforated colon/ischemic colitis. |
| Nov-19-2020 14:57:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Opened | Clinical Please submit a SAE safety followup with information concerning pain control medication following recent TKR; also bowel regimen if any prescribed while using pain control medication |
| Nov-19-2020 14:49:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Opened | Clinical - SAE report states 'acute parotitis which prompted an exploratory laparotomy'; please clarify the connection between parotitis and surgery. |
| Nov-19-2020 14:46:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | Clinical On review of the SAE report for perforated colon/ischemic colitis/constipation, an event of Parotitis treated by clindamycin has been mentioned, yet it does |

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Generated By: (b) (4)

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|--|-----------------|---------------------|-------------------|---|
| | | | | not appear in the CRF. Please review for safety and update AE log CRF accordingly |
| Nov-19-2020 14:38:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | CLINICAL SAE report has updated event term to 3 specific SAEs of 1) Perforated Colon, 2) Ischemic Colitis, and 3) Constipation (cause of previous 2). Please update AE CRF accordingly (ie not with 1 continuous term). |
| Nov-16-2020 14:21:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Clinical Query closed; will follow for SAE update on the unclear reference to COVID sx |
| Nov-16-2020 14:19:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Nov-16-2020 14:07:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Pt reported COVID symptoms on 11SEP2020 which is why the patient was called by the site. It does not relate to the SAE of Bowel problems. This is entered on the SAE narrative to clearly state why the site was calling the patient at the time of report. |
| Nov-16-2020 14:03:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Will update SAE Narrative |

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|---|-----------------|---------------------|--------------------------|--|
| Nov-16-2020 13:51:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | Clinical - Vax 1 fatigue ended 1Sep20 per V2 CRF. If not related to this SAE starting 31Oct20, please remove: "and for follow-up on fatigue that she reported on 7 day of vaccination dose1." from SAE narrative. |
| Nov-16-2020 13:46:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Clinical Bowel problems SAE (#2020443355) has onset date >31Oct20, and SAE narrative states "The subject reported COVID symptoms on >09Nov2020". What does this refer to/which COVID Sx/how related to bowel problems/do COVID illness visit? |
| Nov-16-2020 13:29:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | complaint of fatigue does NOT relate to SAE of Bowel Problems. This is the reason the patient was called by the site which led to her husband reporting that she was currently hospitalized for Bowel Problems. |
| Nov-16-2020 12:43:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Please clarify query |
| Nov-14-2020 18:27:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical - please clarify SAE (2020443355) statement on |

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|--|-----------------|---------------------|--------------------------------------|---|
| | | | | 'followup for fatigue that she reported on 7 day of vaccination dose 1'; how does this complaint in August relate to the SAE of Bowel problems on 31Oct20? Please describe bowel Sx. |
| Nov-14-2020 18:25:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical - please clarify SAE (#2020443355) statement that COVID Sx were reported on 09NOV20, which is after the date of admission on 31Oct20 (ie, reported in advance)? If Sx, please list |
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bowel Problems | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/31/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------|-----------------------------------|
| Dec-01-2020 18:54:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-01-2020 08:51:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | End date is unknown at the moment |
| Nov-25-2020 14:01:54 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINICAL Please |

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| | | | | |
|--|-----------------|---------------------|---------------------------|--|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | submit event Perforated Colon end date if known. |
| Nov-10-2020 12:13:51 (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 |
|--|-----------------|-------------------------|-------------------------|--|
| Nov-24-2020 15:42:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-24-2020 09:58:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | This has been reconciled |
| Nov-24-2020 06:36:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Opened | CLINQUERY: Event, Perforated Colon, is reported to be life-threatening but only reported to be Grade 3. Please refer to protocol 10.3.3 for grading of life-threatening events. Please reconcile entries in fields. |
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

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

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

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------------|
| Nov-24-2020 09:58:34 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |

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| | | | | |
|---|-----------------|------------------|---|---|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p> | |
| Nov-16-2020 13:27:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Query closed; will follow for SAE update with the requested COVID test info |
| Nov-16-2020 12:56:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Will update once medical records are received. It is unknown at this time whether a COVID test was performed. |
| Nov-14-2020 18:21:03 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical COVID test |

| Header Text: c4591001 Visit: Logs - Unscheduled Form Version: 22-Apr-2020 21:02 Site No: 1080 Subject No: 10801013 Generated By: (b) (4) | | | | |
|---|-----------------|------------------------|--|---|
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| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | status (yes/no) during Hosp not reported in this SAE, & COVID symptoms reported. Please submit a follow-up SAE form [#2020443355] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date/result |
| Nov-11-2020 01:25:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Bowel Problems: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability? | Initial Entry |

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| | | | | |
|--|--|--|--|--|
| | | | ty/incapacity? NO Is this serious event life threatening? YES Other medically important serious event YES | |
|--|--|--|--|--|

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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-10-2020 12:13:51 (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 |
|--|-----------------|-------------------------|---|--------------------------|
| Nov-20-2020 11:25:17 (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> Constipation | New Information |
| Nov-13-2020 14:15:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-13-2020 13:58:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |

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9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---|
| Nov-13-2020 13:58:03 (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> A confirmed possible etiology will be entered once it is known. | Changed Information |
| Nov-13-2020 13:24:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Reissued:Opened | CLINQUERY: query closed without change to data, please enter a comment in the field to clarify unknown or to be reviewed |
| Nov-13-2020 12:29:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Comment added |
| Nov-11-2020 18:43:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Reissued:Opened | CLINQUERY: thanks, in the meantime could you please enter a comment in the field to clarify unknown or to be reviewed |
| Nov-11-2020 17:26:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | a confirmed possible etiology will be entered once the patient is out of the hospital and medical records have been received. |
| Nov-11-2020 16:50:48 | ACV0PFEINFP6000 | Hayley | Query 1: Opened | CLINQUERY: |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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) | | Wyper (b) (4) | | Please review this entry and enter a possible etiology for the bowel problems. The current entry is the same as the event term |
| Nov-10-2020 12:13:51 (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> bowel problems | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-10-2020 12:13:51 (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 |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

| | | | | |
|---|-----------------|---------------------|--|-----------------|
| Nov-20-2020 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERING/RESOLVING | New Information |
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RESO LVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-10-2020 12:13:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|-------------------------|
| Nov-15-2020 06:47:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020443355 | corrected AER number |
| Nov-11-2020 01:25:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020443255 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Ischemic colitis | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/31/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 11:24:53 (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 |
|----------------------|-----------------|--------|-----------------|--------------------|
| Nov-24-2020 15:42:44 | ACV0PFEINFP6000 | Hayley | Query 1: Closed | Response satisfies |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1080**Subject No:** 10801013**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**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) | | Wyper (b) (4) | | query |
| Nov-24-2020 09:58:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | This has been reconciled |
| Nov-24-2020 06:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Opened | CLINQUERY: Event, Ischemic Colitis, is reported to be life-threatening but only reported to be Grade 3. Please refer to protocol 10.3.3 for grading of life-threatening events. Please reconcile entries in fields. |
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.****Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------------|
| Nov-24-2020 09:57:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO | Transcription Error |

Header Text: c4591001
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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete
Site Name: (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:11

| | | | | |
|---|-----------------|------------------------|--|--|
| | | | <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p> | |
| Nov-23-2020 04:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Ischemic colitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or</p> | Initial Entry |

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1080**Subject No:** 10801013**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

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

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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 11:24:53 (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 |
|--|-----------------|---------------------|--|---------------|
| Nov-20-2020 11:24:53 (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> Constipation | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

| | | | | |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 11:24:53 (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 |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERING/RESOLVING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 11:24:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Nov-23-2020 04:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020443355 | Initial Entry |

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Constipation | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/31/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------|-------------------|--------------------------------|
| Dec-02-2020 10:49:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Juleen Gayed (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-24-2020 16:09:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | It is unknown at this time. |
| Nov-24-2020 11:41:43 | ACV0PFEINFP6000 | Juleen | Query 1: Opened | Clin: Please confirm |

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Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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| | | | | |
|--|-----------------|---------------------|---------------------------|-----------------------------|
| (UTC-05:00) Eastern Time (US & Canada) | | Gayed (b) (4) | | if this AE is still ongoing |
| Nov-20-2020 11:27:21 (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 |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|--------------------------|
| Nov-24-2020 15:41:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Closed | Response satisfies query |
| Nov-24-2020 09:55:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |
| Nov-24-2020 09:55:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? | Transcription Error |

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1080**Subject No:** 10801013**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

| | | | | |
|---|-----------------|----------------------------|--|--|
| | | | <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p> | |
| Nov-24-2020 06:38:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Opened | CLINQUERY: Event, Constipation, is reported to be life-threatening but only reported to be Grade 3. Please refer to protocol 10.3.3 for grading of life-threatening events. Please reconcile entries in fields. |
| Nov-23-2020 04:55:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Constipation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

| | | | | |
|--|--|--|--|--|
| | | | with congenital anomaly or birth defect? | |
| | | | NO | |
| | | | Did this serious event result in death? | |
| | | | NO | |
| | | | Did this serious event require or prolong hospitalization? | |
| | | | YES | |
| | | | Did this serious event result in persistent or significant disability /incapacity? | |
| | | | NO | |
| | | | Is this serious event life threatening? | |
| | | | YES | |
| | | | Other medically important serious event | |
| | | | YES | |

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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 11:27:21 (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 |
|--|-----------------|---------------------|---|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(| Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

| | | | | |
|--|--|--|---|--|
| | | | s), this event is due to: OTHER If Other, specify: Unknown | |
|--|--|--|---|--|

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 11:27:21 (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 |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERING/RESOLVING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 11:27:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 04:55:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 2020443355 | Initial Entry |

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Header Text: c4591001

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Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-20-2020 16:30:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-20-2020 16:30:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 5 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---|
| Nov-24-2020 09:58:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-24-2020 09:54:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Correct. No prior hx of atrial fibrillation |
| Nov-23-2020 18:40:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | clinical: Thank you. Confirming no prior hx atrial fibrillation in particular |
| Nov-23-2020 15:09:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per medical records, no other heart issues were part of her medical history. |
| Nov-23-2020 14:57:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | clinical: pls advise if subject with prior hx of atrial fibrillation or cardiac disease other than hypertension. Thanks |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Nov-20-2020 16:30:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Atrial Fibrillation | Initial Entry |
|---|-----------------|---------------------|---|---------------|

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-20-2020 16:30:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/11/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 16:30:00 (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 |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-20-2020 16:30:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:30:00 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

| | | | | |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:30:00 (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 |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 16:30:00 (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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 16:30:00 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:30:00 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:30:00 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

| | | | | |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 16:30:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RESOL VED | Initial Entry |
|---|-----------------|---------------------|--|---------------|

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:30:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-20-2020 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-20-2020 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-20-2020 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Diuresis | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/9/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 16:31:09 (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 |
|----------------------|-----------------|------------------|--------------------|---------------|
| Nov-20-2020 16:31:09 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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) | 2 | |
|--|--|---------------------|---|--|

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:31:09 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:31:09 (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 |
|--|-----------------|---------------------|--|---------------|
| Nov-20-2020 16:31:09 (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 |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 16:31:09 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:31:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-20-2020 16:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-20-2020 16:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Nov-20-2020 16:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Acute parotitis | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 16:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/8/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-20-2020 16:31:57 (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 |
|----------------------|-----------------|------------------|--------------------|---------------|
| Nov-20-2020 16:31:57 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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) | 2 | |
|--|--|---------------------|---|--|

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:31:57 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:31:57 (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 |
|--|-----------------|---------------------|--|---------------|
| Nov-20-2020 16:31:57 (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 |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 16:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------|--|
| Nov-24-2020 23:49:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-24-2020 09:56:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-24-2020 09:56:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Transcription Error |
| Nov-23-2020 20:45:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Clinical - Under Con Med given for parotitis; SAE report mentions clindamycin. Please review, and if medicine was prescribed for parotitis, please update |
| Nov-23-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-23-2020 09:38:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Transcription Error |
| Nov-21-2020 16:09:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINICAL Please clarify the non-drug procedure used to treat acute parotitis. |
| Nov-20-2020 16:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Nov-20-2020 16:31:57 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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) | YES | |
|--|--|---------------------|-----|--|

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-20-2020 16:31:57 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 16:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 10:15:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:17:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 10:15:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Transcription Error |
| Aug-11-2020 18:18:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 10:16:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:19:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 10:16:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:19:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 11:11:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:20:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 11:11:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:21:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 11:12:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

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Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 11:13:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:22:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 11:13:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:23:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 11:14:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:23:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Aug-13-2020 11:14:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Aug-11-2020 18:24:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 12:58:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:17:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 12:58:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:17:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 12:58:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

| Aug-11-2020 18:17:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|---|--------------------------|---|---|
| 4. Medication: | | | | |
| <i>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).</i> | | | | |
| Date | Location | User | Value | Reason |
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: C losed | Response satisfies query |
| Aug-13-2020 10:14:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: A nswered | Will be deleted. |
| Aug-13-2020 06:23:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: C losed | Response satisfies query |
| Aug-12-2020 20:04:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 2: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 12:58:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: A nswered | Changed Information |
| Aug-12-2020 12:58:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-12-2020 05:59:20 (UTC-05:00) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: O pened | GPD Clin: Please note, general |

| | | | | |
|---|-----------------|------------------|---|---|
| Eastern Time (US & Canada) | | | | concomitant medications are NOT captured in the CRF for this study. Only prior vaccinations should appear on this page, and any prohibited medications on other pages. Please remove all general medications from the CRF |
| Aug-11-2020 18:17:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bupropion, BID, PO, 1 50 mg | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|------------------------|
| Aug-12-2020 12:58:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 12:58:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Aug-11-2020 18:17:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 12:58:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:18:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 12:58:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:18:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 12:58:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |

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| | | | | |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-11-2020 18:18:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|-----------------|-------------------------|--------------------------|---------------|

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).

| Date | Location | User | Value | Reason |
|---|---|--------------------------|--|--|
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: C losed | Response satisfies query |
| Aug-13-2020 10:15:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | Will be deleted. |
| Aug-12-2020 20:04:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 12:58:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-11-2020 18:18:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Diltiazem, BID, PO, 1 80 mg | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Aug-12-2020 12:59:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 12:58:50 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed |

| | | | | |
|---|-----------------|---------------------|------------------------------------|---------------|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | Information |
| Aug-11-2020 18:18:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 12:59:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Aug-11-2020 18:19:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 3 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 12:59:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Aug-11-2020 18:19:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 12:59:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

| | | | | |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-11-2020 18:19:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|-----------------|-------------------------|--------------------------|---------------|

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).

| Date | Location | User | Value | Reason |
|---|---|--------------------------|---|--|
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: C losed | Response satisfies query |
| Aug-13-2020 10:15:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | Will be deleted. |
| Aug-12-2020 20:05:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 12:59:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-11-2020 18:19:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Quinapril HCL, BID, PO, 20-12. 5 mg | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Aug-12-2020 13:00:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

| | | | | |
|---|-----------------|-----------------------------------|------------------------------------|------------------------|
| Aug-12-2020 12:59:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: | Changed Information |
| Aug-11-2020 18:19:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: UNK/UNK/2020 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------------|
| Aug-12-2020 13:00:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:00:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:19:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------------|
| Aug-12-2020 13:00:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:00:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:19:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------------|
| Aug-12-2020 13:00:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:00:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |

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| Aug-11-2020 18:19:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|---|--------------------------|--------------------------------------|---|
| 4. Medication: | | | | |
| <i>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).</i> | | | | |
| Date | Location | User | Value | Reason |
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Aug-13-2020 10:16:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Will be deleted. |
| Aug-13-2020 00:28:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 2: Opened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 19:56:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Closed | Discrepancy has been closed. |
| Aug-12-2020 13:00:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:00:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Aug-12-2020 13:00:33 (UTC-05:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |

| | | | | |
|---|---|-----------------------|--|---|
| Eastern Time (US & Canada) | | | | |
| Aug-12-2020 04:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Opened | Clarify FOCUS VITAMIN, BID, PO, 1 TAB as follows...The term is unclear. Are you reporting FOCUS MULTI, BID, PO, 1 TAB? FOCUS SELECT, BID, PO, 1 TAB? FOCUS MACULAPRO, BID, PO, 1 TAB? Or other? If so, please update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you. |
| Aug-11-2020 18:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Focus Vitamin, BID, PO, 1 Tab | Transcription Error |
| Aug-11-2020 18:19:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Focus Vitamin | Initial Entry |

| 5. Date: | | | | |
|---|-----------------|------------------|-----------------------------------|---------------------|
| Date | Location | User | Value | Reason |
| Aug-12-2020 13:00:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:00:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |

| | | | | |
|---|-----------------|-----------------------------------|------------------------------------|---------------|
| Aug-11-2020 18:19:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: UNK/UNK/2020 | Initial Entry |
|---|-----------------|-----------------------------------|------------------------------------|---------------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:01:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:01:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Aug-11-2020 18:20:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:01:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:01:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Aug-11-2020 18:20:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:01:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:01:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

| | | | | |
|---|---|--------------------------|--|--|
| Aug-11-2020 18:20:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
| 4. Medication: | | | | |
| <i>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).</i> | | | | |
| Date | Location | User | Value | Reason |
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: C losed | Response satisfies query |
| Aug-13-2020 11:11:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | Will be deleted. |
| Aug-12-2020 20:05:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 13:01:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 13:01:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-11-2020 18:20:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Xiidra, BI D, Drops, 1 Drop | Initial Entry |
| 5. Date: | | | | |
| Date | Location | User | Value | Reason |
| Aug-12-2020 13:01:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:01:23 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed |

| | | | | |
|---|-----------------|---------------------|------------------------------------|---------------|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | Information |
| Aug-11-2020 18:20:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:02:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:01:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Aug-11-2020 18:21:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 6 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:02:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:01:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Aug-11-2020 18:21:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:02:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:01:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

| | | | | |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-11-2020 18:21:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|-----------------|-------------------------|--------------------------|---------------|

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).

| Date | Location | User | Value | Reason |
|---|---|--------------------------|--|---|
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Aug-13-2020 11:11:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Will be deleted. |
| Aug-12-2020 20:05:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Opened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 13:02:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:01:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Aug-11-2020 18:21:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Vitamin C , QD, PO, 500 mg | Transcription Error |
| Aug-11-2020 18:21:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Vitamin C | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

| | | | | |
|---|-----------------|-----------------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:02:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:02:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: | Changed Information |
| Aug-11-2020 18:21:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: UNK/UNK/2020 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:03:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Aug-11-2020 18:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 7 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:03:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Aug-11-2020 18:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:03:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Aug-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

| | | | | |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-11-2020 18:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|-----------------|-------------------------|--------------------------|---------------|

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).

| Date | Location | User | Value | Reason |
|---|---|--------------------------|--|--|
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: C losed | Response satisfies query |
| Aug-13-2020 11:12:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | Will be deleted. |
| Aug-12-2020 20:05:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 13:03:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 13:02:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-11-2020 18:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Ambien, P RN, PO, 3. 3 mg | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Aug-12-2020 13:03:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:02:50 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed |

| | | | | |
|---|-----------------|---------------------|------------------------------------|---------------|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | Information |
| Aug-11-2020 18:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:03:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:03:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:22:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 8 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:03:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:03:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:22:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:03:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:03:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

| | | | | |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-11-2020 18:22:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|-----------------|-------------------------|--------------------------|---------------|

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).

| Date | Location | User | Value | Reason |
|---|---|--------------------------|--|--|
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: C losed | Response satisfies query |
| Aug-13-2020 11:12:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | Will be deleted. |
| Aug-12-2020 20:05:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 13:03:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 13:03:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-11-2020 18:22:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Ranitidine HCL, PRN , PO, 300 mg | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Aug-12-2020 13:03:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

| | | | | |
|---|-----------------|-----------------------------------|------------------------------------|------------------------|
| Aug-12-2020 13:03:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: | Changed Information |
| Aug-11-2020 18:22:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: UNK/UNK/2020 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:04:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:04:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:23:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 9 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:04:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:04:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:23:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:04:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:04:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |

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| | | | | |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-11-2020 18:23:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|-----------------|-------------------------|--------------------------|---------------|

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).

| Date | Location | User | Value | Reason |
|---|---|--------------------------|---|--|
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: C losed | Response satisfies query |
| Aug-13-2020 11:13:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | Will be deleted. |
| Aug-13-2020 00:28:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 13:04:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 13:04:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-11-2020 18:23:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Cetirizine, PRN, PO, 10 Mg | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Aug-12-2020 13:04:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:04:31 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed |

| | | | | |
|---|-----------------|---------------------|------------------------------------|---------------|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | Information |
| Aug-11-2020 18:23:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:04:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:23:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:04:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:23:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:04:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

| | | | | |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-11-2020 18:23:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
|---|-----------------|-------------------------|--------------------------|---------------|

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).

| Date | Location | User | Value | Reason |
|---|---|--------------------------|---|--|
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: C losed | Response satisfies query |
| Aug-13-2020 11:13:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | Will be deleted. |
| Aug-13-2020 00:28:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 13:04:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-11-2020 18:23:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Ibuprofen, PRN, PO, 400 mg | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Aug-12-2020 13:05:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:05:08 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed |

| | | | | |
|---|-----------------|---------------------|------------------------------------|---------------|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | Information |
| Aug-11-2020 18:23:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:05:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:24:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11 | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:05:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Aug-11-2020 18:24:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|------------------------|
| Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:05:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

| | | | | |
|---|---|--------------------------|---|--|
| Aug-11-2020 18:24:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NO | Initial Entry |
| 4. Medication: | | | | |
| <i>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).</i> | | | | |
| Date | Location | User | Value | Reason |
| Aug-14-2020 12:34:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: C losed | Response satisfies query |
| Aug-13-2020 11:14:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | Will be deleted. |
| Aug-12-2020 20:08:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Null Term: Verbatim term must not be null/blank. |
| Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Not Applic able | Initial Entry |
| Aug-12-2020 13:05:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: | Changed Information |
| Aug-11-2020 18:24:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: CBD Oil, P RN, Drops, 600 mg | Initial Entry |
| 5. Date: | | | | |
| Date | Location | User | Value | Reason |
| Aug-12-2020 13:05:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Aug-12-2020 13:05:47 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed |

| | | | | |
|---|-----------------|---------------------|------------------------------------|---------------|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | | Information |
| Aug-11-2020 18:24:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Jan-14-2021 15:57:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/5/2021 | Initial Entry |

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - 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

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I. Select appropriate response - Is participant willing to return for Vaccination 3?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Jan-14-2021 15:58:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-14-2021 15:58:35 (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-14-2021 15:58:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national reco mmendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Jan-14-2021 15:58:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/5/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-14-2021 15:58:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|-----------------------------------|---|
| Jan-22-2021 02:47:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jan-21-2021 14:48:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Query 1: Answered | Changed data per query |
| Jan-20-2021 13:03:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Kindly review and complete 'Inclusion/Exclusion Criteria - Further Vaccination form' at this visit. Thank you. |
| Jan-14-2021 16:00:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-14-2021 16:00:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Jan/14/2021 | 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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-14-2021 16:01:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Jan-14-2021 16:01:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Jan-14-2021 16:01:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-14-2021 16:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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:** 10801013**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 |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-14-2021 16:02:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-14-2021 16:02:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Jan-15-2021 16:49:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Jan-14-2021 23:07:59 (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. |
| Jan-14-2021 16:02:11 (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-14-2021 16:02:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/14/2021 | Initial Entry |

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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-15-2021 16:49:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPTSCX | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-15-2021 16:49:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPTSCX | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-15-2021 16:50:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRT3TN | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-15-2021 16:50:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRT3TN | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-15-2021 16:50:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRT3TR | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-15-2021 16:50:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRT3TR | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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:** 10801013**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 |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-14-2021 16:02:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-14-2021 16:02:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Jan-14-2021 16:31:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-14-2021 16:02:51 (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-14-2021 16:02:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/14/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-14-2021 16:31:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPTS5N | Initial Entry |

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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-14-2021 16:31:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPTS5N | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801013

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

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-14-2021 16:04:16 (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 |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 13:26 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801013

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

| | |
|--------------------|------------------|
| Time (US & Canada) | (b) (4), (b) (6) |
|--------------------|------------------|

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Jan-14-2021 16:04:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|----------------------------------|---------------|
| Feb-04-2021 13:03:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: Feb/4/2021 | Initial Entry |

Header Text: c4591001**Visit:** V102_VAX4**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:21**Form Status:** Data Complete, Frozen, Verified**Site No:** 1080**Site Name:** (1080) PMG Research of Raleigh, LLC dba PMG Research of Cary**Subject No:** 10801013**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Lab Panel:**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|----------------------------------|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: Feb/4/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|---|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|--------------------------------|---------------|
| Feb-04-2021 13:03:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: NOT DONE | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (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:** 10801013**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 |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-04-2021 16:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-04-2021 16:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|--|---|
| Feb-04-2021 16:56:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-04-2021 16:55:36 (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-04-2021 16:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: YES Date of Collection: Feb/4/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|--|---------------|
| Feb-04-2021 16:56:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: Sample ID: BR9R9M | Initial Entry |

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: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|------------------------------|---------------|
| Feb-04-2021 16:56:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: BR9R9M | Initial Entry |

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801013

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

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|--------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|--|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: Feb/4/2021 12:10 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern | ACV0PFEINFP6000 | Mollie Maples | Data Entry: LEFT | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1080

Subject No: 10801013

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

| | |
|--------------------|---------|
| Time (US & Canada) | (b) (4) |
|--------------------|---------|

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|---------------------------|---------------|
| Feb-04-2021 13:04:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1080

Subject No: 10801013

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------------|--|
| Mar-08-2021 17:07:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-08-2021 09:07:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Query 1: Answered | Updated |
| Mar-08-2021 06:03:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103. |
| Mar-05-2021 08:35:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/4/2021 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

Generated By: (b) (4)

Form: CONTACT OUTCOME - 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

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1. Contact Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Mar-05-2021 08:35:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-05-2021 08:35:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Mar/4/2021 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1080

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

Subject No: 10801013

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|----------------------------------|---------------|
| Mar-08-2021 09:06:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: Mar/4/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Mar-08-2021 09:06:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: OPEN LABEL TREATMENT | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|---------------------------------|---------------|
| Mar-08-2021 09:06:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mollie Maples (b) (4) | Data Entry: COMPLETED | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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

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1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-30-2020 17:05:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Aug-11-2020 18:15:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-11-2020 17:49:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|-----------------------------------|--|
| Dec-21-2020 00:25:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-18-2020 10:53:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Patient inadvertently clicked 'yes;' not COVID symptoms present |
| Dec-17-2020 15:19:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 14DEC2020. But there is no COVID Illness visit reported in the database. Please clarify. |
| Sep-30-2020 17:05:41 (UTC-05:00) Eastern | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/30/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1080

Subject No: 10801013

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

| | | | | |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Time (US & Canada) | | | | |
| Aug-11-2020 18:15:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/11/2020 | Initial Entry |
| Aug-11-2020 17:49:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/11/2020 | Initial Entry |

090177e196ae40ce\Final\Final On: 01-Apr-2021 05:44 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1080

Subject No: 10801013

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](#)

1. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-18-2020 16:21:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |