

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

|    |   |                 |
|----|---|-----------------|
| 1. | Select appropriate response - Protocol version                        | 24 JUL 2020     |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Aug/27/2020 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DEMOGRAPHY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [10791199]                                     |
| 2. | Birth Date:                     | (b) (6) /1981                                  |
| 3. | Sex:                            | MALE   |
| 4. | Ethnicity:                      | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE  |
| 6. | Racial Designation:             |  |

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Aug/27/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

|    |   |                         |
|----|---|-------------------------|
| 1. | Description of Inclusion Criterion<br>Not Met | Not Applicable<br>_____ |
|----|---|-------------------------|

**Exclusion Criteria Met**

|    |   |                         |
|----|---|-------------------------|
| 2. | Description of Exclusion<br>Criterion Met | Not Applicable<br>_____ |
|----|---|-------------------------|

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DISPOSITION - SCREENING

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Aug/27/2020 |
| 2. | Phase of Disposition:                    | SCREENING   |
| 3. | Status:                                  | COMPLETED   |
| 4. | Specify Status:                          | [ ]         |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

|     |  |   |
|-----|--|---|
| 1.a | Line/MH Number:  | [1]   |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Anxiety (Mild)]                                |
|     | Start Date:  | UNK/UNK/2015                                    |
|     | Ongoing:   | YES   |
| 1.b | Line/MH Number:  | [2]   |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Attention Deficit Hyper Disorder (ADHD)- Mild] |
|     | Start Date:  | UNK/UNK/2018                                    |
|     | Ongoing:   | YES   |
| 1.c | Line/MH Number:  | [3]   |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Benign Prostatic Hyperplasia (BPH)]            |
|     | Start Date:  | UNK/UNK/2018                                    |
|     | Ongoing:   | YES   |
| 1.d | Line/MH Number:  | [4]   |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Alopecia]                                      |
|     | Start Date:  | UNK/UNK/2018                                    |
|     | Ongoing:   | YES   |

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**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Aug/27/2020 |
| 2. | Weight:          | [190.0]     |
| 3. | Unit:            | LB          |
| 4. | Height:          | [71.0]      |
| 5. | Unit:            | in          |
| 6. | Body Mass Index: | [26.5]      |

**Vital Signs Details**

|     |                       |          |
|-----|-----------------------|----------|
| 7.a | Record Identifier:    | 1        |
|     | Temperature:          | [97.4]   |
|     | Unit:                 | F        |
|     | Temperature Location: | FOREHEAD |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Aug/27/2020 |
| 2. | Randomization Number: | [70454]     |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Aug/27/2020 |
| 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 | [BMPYPS] |
| 5.b | Sample ID | [BPCSF4] |
| 5.c | Sample ID | [BPXVNM] |
| 5.d | Sample ID | [BPXVNN] |
| 5.e | Sample ID | [BPXVNP] |

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**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Aug/27/2020 |
| 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 | [BPXVM8] |
|-----|-----------|----------|

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**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Aug/27/2020 17:03                         |
| 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                                       |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

|    |  |  |
|----|--|--|
| 1. | Select appropriate response -<br>Reactogenicity diary collection | NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT |
|----|--|--|

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Sep/16/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Sep/16/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |          |
|-----|-----------------------|----------|
| 2.a | Record Identifier:    | 1        |
|     | Temperature:          | [98.0]   |
|     | Unit:                 | F        |
|     | Temperature Location: | FOREHEAD |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Sep/16/2020 |
| 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 | [BPY408] |
|-----|-----------|----------|

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Sep/16/2020 13:48                         |
| 5.  | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.  | Body Side:  | LEFT                                      |
| 7.  | Route:  | INTRAMUSCULAR                             |
| 8.  | Actual Dose:  | [ ]                                       |
| 9.  | Unit:   |   |
| 10. | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Oct/19/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BSH8LM] |
| 5.b | Sample ID | [BSH8L8] |
| 5.c | Sample ID | [BPB0WT] |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (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:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Date of Visit**

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

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Signs and Symptoms**

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

**Symptoms**

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

**Symptoms - Other**

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Illness Details**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Date of Visit**

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

**COVID-19 Illness Visit**

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



**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DISPOSITION - TREATMENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death : | Oct/19/2020 |
| 2. | Phase of Disposition:                      | VACCINATION |
| 3. | Status:                                    | COMPLETED   |
| 4. | Specify Status:                            | [ ]         |

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Date of Visit**

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

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

| #  | Category      | AE Identifier | Adverse Event | Start Date         | Is the Adverse Event Still On going | Form Instance                   |
|----|---------------|---------------|---------------|--------------------|-------------------------------------|---------------------------------|
| 1. | ADVERSE EVENT | 1             | Seizure       | Mar/3/2021 UNK:UNK | YES                                 | <a href="#">Repeating Pages</a> |



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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

**Adverse Event Report**

|    |   |  |
|----|---|--|
| 1. | Category:   | ADVERSE EVENT  |
| 2. | AE ID:  | [1]  |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Seizure]  |
| 4. | Start Date Time:  | Mar/3/2021 UNK:UNK   |
| 5. | Is the adverse event still ongoing?   | YES  |
| 6. | Toxicity Grade:   | 4  |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>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<br><br>Is this serious event associated with congenital anomaly or birth defect?<br>NO<br><br>Did this serious event result in death?<br>NO<br><br>Did this serious event require or prolong hospitalization?<br>YES<br><br>Did this serious event result in persistent or significant disability/incapacity?<br>NO<br><br>Is this serious event life threatening?<br>YES<br><br>Other medically important serious event<br>NO |
| 8. | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log.   | NO   |
| 9. | Is this event related to study treatment:   | NOT RELATED<br><br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br><br>If Other, specify:<br>[Unknown]   |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

|     |  |                      |
|-----|--|----------------------|
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE       |
| 11. | Was a Concomitant Medication given?  | YES                  |
| 12. | Was a Non-Drug Treatment given?  | NO                   |
| 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:<br>For Pfizer Use Only                       | [2021260697]         |

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Medication Error**

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

|     |   |     |
|-----|---|-----|
| 1.  | What is the medication identifier?  | [ ] |
| 2.  | Category:   |     |
| 3.  | Concomitant Medications<br>Pre-specified:   |     |
| 4.  | Medication:<br><br>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?  |     |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Vaccination**

|     |   |     |
|-----|---|-----|
| 1.  | Was there a temporary delay of vaccination?   |     |
| 2.  | Treatment Name  | [ ] |
| 3.  | Formulation:  |     |
| 4.  | Dose Date Time:   | //  |
| 5.  | Anatomical Location:  |     |
| 6.  | Body Side:  |     |
| 7.  | Route:  |     |
| 8.  | Actual Dose:  | [ ] |
| 9.  | Unit:   |     |
| 10. | Timeframe Subject Was Observed  |     |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? |     |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: |  |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Feb/12/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** TREATMENT UNBLINDED

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Feb/12/2021                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** WITHDRAWAL OF CONSENT

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

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

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

|    |                              |                               | <a href="#">Comments</a> |
|----|------------------------------|-------------------------------|--------------------------|
| 1. | Withdrawal of Consent Date : | Not Applicable<br>_____<br>// |                          |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DEATH DETAILS CODED

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

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

**Subject Initials:** ---

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

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

**Death Details**

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

**Cause of Death**

|    |                        |                                |
|----|------------------------|--------------------------------|
| 2. | Cause of Death Status: | Not Applicable<br>_____        |
|    | Cause of Death:        | Not Applicable<br>_____<br>[ ] |

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |             |
|----|---------------------|-------------|
| 1. | Subject Status      | FOLLOW-UP   |
| 2. | Subject Status Date | Oct/19/2020 |

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

|    |                    |                                      |
|----|--------------------|--------------------------------------|
| 1. | Casebook Signature | <a href="#">Click Here to Enable</a> |
|----|--------------------|--------------------------------------|

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

[Audit Trail](#)

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

- CRF\_Sign

| Name        | Signature Meaning | Date  | Type | Action |
|-------------|-------------------|---|------|--------|
| George Raad | Approved          | Mar-12-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

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

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

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| Form | Aug-28-2020 21:00:42 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

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

**Subject Initials:** ---

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

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| Form | Feb-15-2021 15:02:23 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

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

**Subject Initials:** ---

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

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| 1    | Feb-15-2021 15:02:23 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DEATH DETAILS CODED - Comments

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

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

**Subject Initials:** ---

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

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| Form | Feb-15-2021 15:02:40 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DEATH DETAILS CODED - Comments

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

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

**Subject Initials:** ---

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

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| 1    | Feb-15-2021 15:02:40 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791199

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF\_Sign

| Name        | Signature Meaning | Date  | Type | Action |
|-------------|-------------------|---|------|--------|
| George Raad | Approved          | Mar-12-2021 14:42:18 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-11-2021 17:19:54 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|             |          |   |      |        |
|-------------|----------|---|------|--------|
| George Raad | Approved | Mar-10-2021 19:19:34 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-15-2021 15:01:23 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

|             |          |   |      |        |
|-------------|----------|---|------|--------|
| George Raad | Approved | Jan-22-2021 10:43:24 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-24-2020 13:57:57 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|             |          |   |      |        |
|-------------|----------|---|------|--------|
| George Raad | Approved | Oct-27-2020 13:50:02 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Oct-22-2020 17:21:34 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|             |          |   |      |        |
|-------------|----------|---|------|--------|
| George Raad | Approved | Oct-21-2020 14:37:02 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

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

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-28-2020 20:59:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>24 JUL 2020 | Initial Entry |

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

| Date  | Location        | User             | Value                                 | Reason        |
|---|-----------------|------------------|---------------------------------------|---------------|
| Aug-28-2020 20:59:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

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**I. Consent Was:**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-28-2020 20:59:52<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Aug/27/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

[Back to Form](#)

**1. Subject ID**

| Date  | Location        | User                    | Value                          | Reason                            |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Aug-28-2020 20:59:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>10791199 | Item copied from<br>previous form |

**2. Birth Date:**

| Date  | Location        | User                    | Value                               | Reason           |
|---|-----------------|-------------------------|-------------------------------------|------------------|
| Aug-28-2020 20:59:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6) /1981 | Enrollment Entry |

**3. Sex:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-28-2020 21:00:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>MALE | Initial Entry |

**4. Ethnicity:**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-28-2020 21:00:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT HISPANIC OR LATINO(A)<br>OR OF SPANISH ORIGIN | Initial Entry |

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

| Date  | Location        | User             | Value                       | Reason        |
|---|-----------------|------------------|-----------------------------|---------------|
| Aug-28-2020 21:00:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

*I. Date of Visit*

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-28-2020 21:00:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/27/2020 | Initial Entry |

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

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

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-28-2020 21:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/27/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-28-2020 21:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date  | Location        | User             | Value                           | Reason        |
|---|-----------------|------------------|---------------------------------|---------------|
| Aug-28-2020 21:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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*I.a*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-28-2020 21:02:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 1<br><b>Medical History Term:</b> Anxiety (Mild )<br><b>Start Date:</b> UNK/UNK/2015<br><b>Ongoing:</b> YES | Initial Entry |

*I.a Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-28-2020 21:02:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

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

| Date  | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Aug-28-2020 21:02:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Anxiety (Mild) | Initial Entry |

*I.a Start Date:*

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Aug-28-2020 21:02:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>UNK/UNK/2015 | Initial Entry |

*I.a Ongoing:*

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Aug-28-2020 21:02:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

*I.b*

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-28-2020 21:03:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH</b> 2<br><b>Number:</b><br><b>Medical History Term:</b> Attention Deficit Hyper Disorder (ADHD)-<br>: Mild<br><b>Start Date:</b> UNK/UNK/2018<br><b>Ongoing:</b> YES | Initial Entry |

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-28-2020 21:03:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

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

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-28-2020 21:03:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Attention Deficit Hyper Disorder (ADHD)- Mild | Initial Entry |

**1.b Start Date:**

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Aug-28-2020 21:03:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>UNK/UNK/2018 | Initial Entry |

**1.b Ongoing:**

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Aug-28-2020 21:03:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.c**

| Date                 | Location        | User      | Value              | Reason        |
|----------------------|-----------------|-----------|--------------------|---------------|
| Aug-28-2020 21:05:07 | ACV0PFEINFP6000 | auto calc | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

|  |  |            |   |
|--|--|------------|---|
| (UTC-05:00) Eastern Time (US & Canada) |  | (autocalc) | <b>Line/MH Number:</b> 3<br><b>Medical History Term:</b> Benign Prostatic Hyperplasia (BPH)<br><b>Start Date:</b> UNK/UNK/2018<br><b>Ongoing:</b> YES |
|--|--|------------|---|

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

| Date  | Location        | User                 | Value                | Reason        |
|---|-----------------|----------------------|----------------------|---------------|
| Aug-28-2020 21:05:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 3 | Initial Entry |

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

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-28-2020 21:05:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> Benign Prostatic Hyperplasia (BPH) | Initial Entry |

**I.c Start Date:**

| Date  | Location        | User             | Value                           | Reason        |
|---|-----------------|------------------|---------------------------------|---------------|
| Aug-28-2020 21:05:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> UNK/UNK/2018 | Initial Entry |

**I.c Ongoing:**

| Date  | Location        | User             | Value                  | Reason        |
|---|-----------------|------------------|------------------------|---------------|
| Aug-28-2020 21:05:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> YES | Initial Entry |

**I.d**

| Date  | Location        | User                 | Value  | Reason        |
|---|-----------------|----------------------|--|---------------|
| Aug-28-2020 21:05:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> <b>Line/MH Number:</b> 4<br><b>Medical History Term:</b> Alopecia | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

|  |  |  |                    |              |  |
|--|--|--|--------------------|--------------|--|
|  |  |  | <b>Start Date:</b> | UNK/UNK/2018 |  |
|  |  |  | <b>Ongoing:</b>    | YES          |  |

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-28-2020 21:05:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

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

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Aug-28-2020 21:05:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Alopecia | Initial Entry |

**1.d Start Date:**

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Aug-28-2020 21:05:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>UNK/UNK/2018 | Initial Entry |

**1.d Ongoing:**

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Aug-28-2020 21:05:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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**1. Date:**

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Aug/27/2020 | Initial Entry |

**2. Weight:**

| Date  | Location        | User             | Value                       | Reason        |
|---|-----------------|------------------|-----------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>190.0 | Initial Entry |

**3. Unit:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>LB | Initial Entry |

**4. Height:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>71.0 | Initial Entry |

**5. Unit:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>in | Initial Entry |

**6. Body Mass Index:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>26.5 | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

7.a

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b> 1<br>:<br><b>Temperature:</b> 97.4<br><b>Temperature Unit</b> F<br>:<br><b>Temperature Loca</b> FOREHE<br><b>tion::</b> AD | Initial Entry |

7.a Record Identifier:

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

7.a Temperature:

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>97.4 | Initial Entry |

7.a Unit:

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>F | Initial Entry |

7.a Temperature Location:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Aug-28-2020 21:06:45<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

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**1. Randomization Date :**

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-28-2020 21:07:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/27/2020 | Initial Entry |

**2. Randomization Number:**

| Date  | Location        | User             | Value                       | Reason        |
|---|-----------------|------------------|-----------------------------|---------------|
| Aug-28-2020 21:07:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>70454 | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1079**Site Name:** (1079) PMG Research of Charlotte LLC**Subject No:** 10791199**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-28-2020 21:07:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-28-2020 21:07:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value   | Reason  |
|---|-----------------|---------------------------|---|---|
| Aug-28-2020 21:09:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query  |
| Aug-28-2020 21:07:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Aug-28-2020 21:07:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/27/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-28-2020 21:09:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BMPYPS | Initial Entry |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791199

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-28-2020 21:09:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BMPYPS | Initial Entry |

5.b

| Date  | Location        | User             | Value                                   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-28-2020 21:09:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Sample ID: BPCSF4 | Initial Entry |

5.b Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-28-2020 21:09:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BPCSF4 | Initial Entry |

5.c

| Date  | Location        | User             | Value                                   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-28-2020 21:09:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Sample ID: BPXVNM | Initial Entry |

5.c Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-28-2020 21:09:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BPXVNM | Initial Entry |

5.d

| Date  | Location        | User             | Value                                   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-28-2020 21:10:08<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Sample ID: BPXVNM | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791199

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-28-2020 21:10:08<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BPXVNN | Initial Entry |

5.e

| Date  | Location        | User             | Value                                   | Reason              |
|---|-----------------|------------------|---|---------------------|
| Nov-24-2020 13:57:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Sample ID: BPXVNP | Transcription Error |
| Aug-28-2020 21:10:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Sample ID: VPXVNP | Initial Entry       |

5.e Sample ID

| Date  | Location        | User             | Value                        | Reason              |
|---|-----------------|------------------|------------------------------|---------------------|
| Nov-24-2020 13:57:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BPXVNP | Transcription Error |
| Aug-28-2020 21:10:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>VPXVNP | Initial Entry       |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1079**Site Name:** (1079) PMG Research of Charlotte LLC**Subject No:** 10791199**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-28-2020 21:07:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-28-2020 21:07:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value   | Reason  |
|---|-----------------|---------------------------|---|---|
| Aug-28-2020 21:08:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query  |
| Aug-28-2020 21:07:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Aug-28-2020 21:07:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/27/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-28-2020 21:08:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPXVM8 | Initial Entry |

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-28-2020 21:08:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BPXVM8 | Initial Entry |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Aug-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User             | Value                                   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/27/2020 17:03 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OB<br>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-28-2020 21:08:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-28-2020 21:08:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO - REACTOGENICITY E-<br>DIARY NOT COLLECTED F<br>OR THIS SUBJECT | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Sep-19-2020 16:47:01<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Sep/16/2020 | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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**1. Date:**

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Sep-19-2020 16:47:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sep/16/2020 | Initial Entry |

**2.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-19-2020 16:47:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b> 1<br>:<br><b>Temperature:</b> 98.0<br><b>Temperature Unit</b> F<br>:<br><b>Temperature Loca</b> FOREHE<br><b>tion::</b> AD | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-19-2020 16:47:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Sep-19-2020 16:47:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>98.0 | Initial Entry |

**2.a Unit:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-19-2020 16:47:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>F | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

**2.a Temperature Location:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-19-2020 16:47:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791199

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-19-2020 16:47:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-19-2020 16:47:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value   | Reason  |
|---|-----------------|---------------------------|---|---|
| Sep-19-2020 16:47:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query  |
| Sep-19-2020 16:47:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Sep-19-2020 16:47:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Sep/16/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-19-2020 16:47:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPY408 | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-19-2020 16:47:51<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BPY408 | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User             | Value                                   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sep/16/2020 13:48 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Sep-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

7. Route:

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Sep-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OB<br>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-19-2020 16:48:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-19-2020 20:26:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/19/2020 | 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:** 1079**Site Name:** (1079) PMG Research of Charlotte LLC**Subject No:** 10791199**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-19-2020 20:27:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-19-2020 20:27:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value   | Reason  |
|---|-----------------|---------------------------|---|---|
| Oct-19-2020 20:27:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query  |
| Oct-19-2020 20:27:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Oct-19-2020 20:27:21<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/19/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-19-2020 20:27:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BSH8LM | Initial Entry |

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1079

Site Name: (1079) PMG Research of Charlotte LLC

Subject No: 10791199

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-19-2020 20:27:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BSH8LM | Initial Entry |

5.b

| Date  | Location        | User                | Value                                   | Reason              |
|---|-----------------|---------------------|---|---------------------|
| Oct-22-2020 17:21:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <u>Data Entry:</u><br>Sample ID: BSH8L8 | Transcription Error |
| Oct-19-2020 20:27:55<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Sample ID: BSH8L7 | Initial Entry       |

5.b Sample ID

| Date  | Location        | User                | Value                        | Reason              |
|---|-----------------|---------------------|------------------------------|---------------------|
| Oct-22-2020 17:21:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <u>Data Entry:</u><br>BSH8L8 | Transcription Error |
| Oct-19-2020 20:27:55<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BSH8L7 | Initial Entry       |

5.c

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-19-2020 20:28:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Sample ID: BPB0WT | Initial Entry |

5.c Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-19-2020 20:28:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BPB0WT | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-19-2020 20:28:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/19/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-19-2020 20:28:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date  | Location        | User                | Value                           | Reason        |
|---|-----------------|---------------------|---------------------------------|---------------|
| Oct-19-2020 20:28:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

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

**Form Status:**

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

**Subject Initials:** ---

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

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**3. Adverse Event:**

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

| Date  | Location        | User                | Value                         | Reason   |
|---|-----------------|---------------------|-------------------------------|--|
| Mar-12-2021 15:36:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed               | Response satisfies<br>query  |
| Mar-12-2021 13:18:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered             | We are still waiting<br>on Medical records.  |
| Mar-11-2021 19:36:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened               | Clinical - please<br>clarify if seizure was<br>grand mal; also what<br>workup/evaluation<br>the subject had in<br>hospital |
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Seizure | Initial Entry  |

**4. Start Date Time:**

| Date  | Location        | User                | Value                                    | Reason        |
|---|-----------------|---------------------|--|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/3/2021 UNK:UNK | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

5. Is the adverse event still ongoing?

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

6. Toxicity Grade:

| Date  | Location        | User                | Value                   | Reason        |
|---|-----------------|---------------------|-------------------------|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>4 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date  | Location        | User                      | Value   | Reason  |
|---|-----------------|---------------------------|---|---|
| Mar-12-2021 10:20:01<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query  |
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | For AE Seizure:<br>Response to "Is the<br>adverse event<br>serious?" is 'Yes'<br>but "Serious<br>Adverse Event<br>Number" is blank. |
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Is this serious event associated<br>with congenital anomaly or birth<br>defect?<br><br>NO<br><br>Did this serious event result in d<br>eath? | Initial Entry   |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

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

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-11-2021 17:19:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Mar-11-2021 17:19:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment (s), this event is due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>Unknown | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

| Date  | Location        | User                | Value                                | Reason        |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

| Date  | Location        | User                | Value                                      | Reason        |
|---|-----------------|---------------------|--|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>RECOVERING/RESOLVING | Initial Entry |

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

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-11-2021 17:19:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**15. Serious Adverse Event Number: For Pfizer Use Only**

| Date  | Location        | User             | Value                            | Reason        |
|---|-----------------|------------------|----------------------------------|---------------|
| Mar-12-2021 10:20:01<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>2021260697 | Initial Entry |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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*I. Date of Visit*

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Feb-15-2021 15:01:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Feb/12/2021 | Initial Entry |

**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1079**Subject No:** 10791199**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1079) PMG Research of Charlotte LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

| Date  | Location        | User                      | Value  | Reason  |
|---|-----------------|---------------------------|--|---|
| Feb-15-2021 15:02:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query  |
| Feb-15-2021 15:01:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(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. |
| Feb-15-2021 15:01:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>Participant is willing to return for Vaccination 3<br>Participant is:<br><br>eligible and NOT confirmed to have received only placebo at Vaccination 1/2 | Initial Entry   |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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**I. Date Treatment Unblinded :**

| Date   | Location                                  | User                      | Value   | Reason   |
|--|---|---------------------------|---|--|
| Feb-24-2021<br>18:28:08<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)      | Query<br>1: Clo<br>sed                            | Auto closed by<br>Validation Check:<br>VC_DS001_36   |
| Feb-24-2021<br>09:27:59<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery) | Query<br>1: An<br>swere<br>d                      | Transcription Error  |
| Feb-24-2021<br>09:27:59<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)          | <b>Data<br/>Entry</b><br>:<br>Feb/1<br>2/202<br>1 | Transcription Error  |
| Feb-24-2021<br>02:57:23<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)          | Query<br>1: Rei<br>ssued:<br>Opene<br>d           | DM: Form unfrozen,<br>kindly review and<br>update.   |
| Feb-23-2021<br>15:32:21<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)          | Query<br>1: An<br>swere<br>d                      | Please unfreeze so I<br>can update!  |
| Feb-23-2021<br>06:31:32<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)      | Query<br>1: Op<br>ened                            | DMW7351871;Date<br>Treatment Unblinded<br>should be equal to or<br>after DOV in REVAX<br>CONTACT visit when<br>Reason is ASSESS<br>ELIGIBILITY FOR |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

|   |                 |                  |                                      |  |
|---|-----------------|------------------|--------------------------------------|--|
|   |                 |                  |                                      | ADDITIONAL VACCINATION. Please review and update as appropriate. |
| Feb-15-2021 15:02:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry</b><br>:<br>Feb/8/2021 | Initial Entry  |

**2. Primary Reason for Unblinding:**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Feb-15-2021 15:02:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

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

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

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

**Subject Initials:** ---

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

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**1. Withdrawal of Consent Date :**

| Date  | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Feb-15-2021 15:02:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1079

**Subject No:** 10791199

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

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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

| <b>Date</b>   | <b>Location</b> | <b>User</b>      | <b>Value</b>                         | <b>Reason</b> |
|---|-----------------|------------------|--------------------------------------|---------------|
| Feb-15-2021 15:02:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1079

Subject No: 10791199

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1079) PMG Research of Charlotte LLC

Subject Initials: ---

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

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**I. Subject Status**

| Date   | Location        | User                    | Value                                     | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-19-2020 20:28:49<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Aug-28-2020 21:07:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Aug-28-2020 21:01:04<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry |

**2. Subject Status Date**

| Date   | Location        | User                    | Value                             | Reason  |
|--|-----------------|-------------------------|-----------------------------------|---|
| Mar-11-2021 19:30:37<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Closed                   | Response satisfies query  |
| Mar-11-2021 17:20:12<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Answered                 | Changed data per query  |
| Mar-11-2021 12:57:30<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Opened                   | CLINICAL - SAE report (#2021260697) received for event of Seizure; please enter the event on the AE log CRF |
| Oct-19-2020 20:28:49<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/19/2020 | Initial Entry   |
| Aug-28-2020 21:07:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Aug/27/2020 | Initial Entry   |
| Aug-28-2020 21:01:04<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Aug/27/2020 | Initial Entry   |

090177e196ae2f22\Final\Final On: 01-Apr-2021 03:35 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1079

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

**Subject No:** 10791199

**Subject Initials:** ---

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

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

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*I. Casebook Signature*

| Date  | Location        | User                | Value                                      | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-21-2020 12:28:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |