

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[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                        | 30 JUN 2020     |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Aug/18/2020 |
|----|--------------|--|

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [12312080]                                 |
| 2. | Birth Date:                     | (b) (6) /1995                              |
| 3. | Sex:                            | MALE                                       |
| 4. | Ethnicity:                      | HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE                                      |
| 6. | Racial Designation:             |  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** DATE OF VISIT

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Aug/18/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

**Inclusion Criteria**

|     |                                     |  |
|-----|-------------------------------------|--|
| 1.a | Inclusion Number:                   | 1  |
|     | Criterion Description:              | Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN01A00  |
| 1.b | Inclusion Number:                   | 2  |
|     | Criterion Description:              | Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures                  |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN02A00  |
| 1.c | Inclusion Number:                   | 3  |
|     | Criterion Description:              | Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study                |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN03A00  |

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|     |                                     |   |
|-----|-------------------------------------|---|
| 1.d | Inclusion Number:                   | 4   |
|     | Criterion Description:              | Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol |
|     | Criterion met?                      | YES   |
|     | Criterion ID: (For Pfizer use only) | IN04A00   |

**Exclusion Criteria**

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.a | Exclusion Number:                   | 1   |
|     | Criterion Description:              | Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX01A00   |

|     |                                     |  |
|-----|-------------------------------------|--|
| 2.b | Exclusion Number:                   | 2  |
|     | Criterion Description:              | Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX02A00  |

|     |                                     |  |
|-----|-------------------------------------|--|
| 2.c | Exclusion Number:                   | 3  |
|     | Criterion Description:              | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX03A00  |

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.d | Exclusion Number:                   | 4   |
|     | Criterion Description:              | Receipt of medications intended to prevent COVID-19   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX04A00   |
| 2.e | Exclusion Number:                   | 8   |
|     | Criterion Description:              | Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination                   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX08A00   |
| 2.f | Exclusion Number:                   | 10  |
|     | Criterion Description:              | Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX10A00   |
| 2.g | Exclusion Number:                   | 11  |
|     | Criterion Description:              | Women who are pregnant or breastfeeding   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX11A00   |

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.h | Exclusion Number:                   | 12  |
|     | Criterion Description:              | Previous vaccination with any coronavirus vaccine   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX12A00   |
| 2.i | Exclusion Number:                   | 13  |
|     | Criterion Description:              | Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids  |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX13A01   |
| 2.j | Exclusion Number:                   | 15  |
|     | Criterion Description:              | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX14A01   |
| 2.k | Exclusion Number:                   | 16  |
|     | Criterion Description:              | Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation                 |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX15A01   |

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.1 | Exclusion Number:                   | 17  |
|     | Criterion Description:              | Previous participation in other studies involving study intervention containing lipid nanoparticles   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX16A01   |
| 2.m | Exclusion Number:                   | 22  |
|     | Criterion Description:              | Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX21A01   |

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Disposition - Screening**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Aug/18/2020 |
| 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:** 1231

**Subject No:** 12312080

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Medical History Details**

|     |  |                    |
|-----|--|--------------------|
| 1.a | Line/MH Number:  | [1]                |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Smoking]          |
|     | Start Date:  | May/1/2008         |
|     | Ongoing:   | YES                |
| 1.b | Line/MH Number:  | [2]                |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Seasonal allergy] |
|     | Start Date:  | Apr/1/2010         |
|     | Ongoing:   | YES                |

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Aug/18/2020 |
| 2. | Weight:          | [107.0]     |
| 3. | Unit:            | kg          |
| 4. | Height:          | [178.0]     |
| 5. | Unit:            | cm          |
| 6. | Body Mass Index: | [33.8]      |

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 7.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.2]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** RANDOMIZATION

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Aug/18/2020 |
| 2. | Randomization Number: | [55186]     |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45[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/18/2020 |
| 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 | [BPHYH4] |
| 5.b | Sample ID | [BPHYH5] |
| 5.c | Sample ID | [BHY45F] |
| 5.d | Sample ID | [BHY45G] |
| 5.e | Sample ID | [BHY45H] |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Aug/18/2020 |
| 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 | [BHWTP3] |
|-----|-----------|----------|

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** VACCINATION

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[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/18/2020 17:35                         |
| 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                                       |

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response - 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:** 1231

**Subject No:** 12312080

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

**Form:** DATE OF VISIT

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Sep/8/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |            |
|----|-------|------------|
| 1. | Date: | Sep/8/2020 |
|----|-------|------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.5]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[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/8/2020 |
| 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 | [BP2DDD] |
|-----|-----------|----------|

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** VACCINATION

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[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/8/2020 14:55                          |
| 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                                       |

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**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Oct/6/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[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/6/2020 |
| 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 | [BNV61J] |
| 5.b | Sample ID | [BNV614] |
| 5.c | Sample ID | [BP1VRC] |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** DATE OF VISIT

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Mar/15/2021 |
| 2. | Erroneous Visit |             |



**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Mar/15/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BRYHGX] |
| 5.b | Sample ID | [BRYHJM] |
| 5.c | Sample ID | [BPT6CP] |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 28-Mar-2021 02:35

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)



**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 28-Mar-2021 02:23

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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? |  |
|----|--|--|

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**Date of Visit**

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

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Not Started

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231    **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 16:45

**Unplanned Assessments**

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Oct/6/2020  |
| 2. | Phase of Disposition:                       | VACCINATION |
| 3. | Status:                                     | COMPLETED   |
| 4. | Specify Status:                             | [ ]         |



**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 28-Mar-2021 02:28

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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? |     |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Feb/4/2021 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

|    |              |   |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Feb/4/2021 |
|----|--------------|---|

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312080**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BLBGJB] |
| 5.b | Sample ID | [BLBGJ3] |
| 5.c | Sample ID | [BPWD53] |

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[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>Feb/4/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                      |

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/16/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Surveillance Visit**

|    |                              |             |
|----|------------------------------|-------------|
| 3. | COVID-19 Surveillance Visit: | SSWAB_WEEK2 |
|----|------------------------------|-------------|

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/16/2021

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[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>Feb/16/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP87WB] |
|-----|-----------|----------|

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/26/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Feb/26/2021 |
| 2. | Erroneous Visit |             |

**COVID-19 Surveillance Visit**

|    |                              |             |
|----|------------------------------|-------------|
| 3. | COVID-19 Surveillance Visit: | SSWAB_WEEK4 |
|----|------------------------------|-------------|

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/26/2021

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[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>Feb/26/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP1Z44] |
|-----|-----------|----------|

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)



**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/08/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Mar/8/2021 |
| 2. | Erroneous Visit |            |

**COVID-19 Surveillance Visit**

|    |                              |             |
|----|------------------------------|-------------|
| 3. | COVID-19 Surveillance Visit: | SSWAB_WEEK6 |
|----|------------------------------|-------------|

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/08/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45[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>Mar/8/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                      |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BR22D6] |
|-----|-----------|----------|

**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

| Date of Visit |                 |            |
|---------------|-----------------|------------|
| 1.            | Date of Visit   | Mar/8/2021 |
| 2.            | Erroneous Visit |            |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[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<br>Vaccination 1/2 |
|----|---|---|

**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

| #  | Category      | AE Identifier | Adverse Event            | Start Date        | Is the Adverse Event Still Ongoing       | Form Instance                   |
|----|---------------|---------------|--------------------------|-------------------|--|---------------------------------|
| 1. | ADVERSE EVENT | 1             | left inguinal adenopathy | Oct/20/2020 10:30 | NO<br>End Date Time:<br>Nov/3/2020 09:00 | <a href="#">Repeating Pages</a> |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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[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)  | [left inguinal adenopathy]               |
| 4. | Start Date Time:  | Oct/20/2020 10:30                        |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/3/2020 09:00 |
| 6. | Toxicity Grade:   | 1  |
| 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). | 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                                       |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12312080**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45

|     |  |  |
|-----|--|--|
| 9.  | Is this event related to study treatment:                                  | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[unknown] |
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE   |
| 11. | Was a Concomitant Medication given?  | NO   |
| 12. | Was a Non-Drug Treatment given?  | NO   |
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED   |
| 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                       | [ ]  |

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

| #  | 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:** 1231

**Subject No:** 12312080

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Medication Error**

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

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

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Concomitant Medications**

|    |   |     |
|----|---|-----|
| 1. | What is the medication identifier?  | [ ] |
| 2. | Category:   |     |
| 3. | Concomitant Medications 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:   | //  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Concomitant Medications**

|     |   |     |
|-----|---|-----|
| 1.  | What is the medication identifier?  | [ ] |
| 2.  | Category:   |     |
| 3.  | Concomitant Medications 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?  |     |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

**Header Text:** C4591001

**Visit:**  
UNPLANNED\_BOOSTER\_CONTACT -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**Date of Visit**

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

**Header Text:** C4591001

**Visit:**  
UNPLANNED\_BOOSTER\_CONTACT -  
Unscheduled

**Form:** BOOSTER DOSE TRIGGER FORM

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**Booster Dose Trigger Form**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response -<br>Will the participant return for<br>consent/eligibility assessment<br>for the booster dose visit? |  |
|----|---|--|

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Mar/8/2021                                    |
| 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:** 1231

**Subject No:** 12312080

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Withdrawal Of Consent**

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**Death Details**

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

**Cause of Death**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |            |
|----|---------------------|------------|
| 1. | Subject Status      | FOLLOW-UP  |
| 2. | Subject Status Date | Oct/6/2020 |

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**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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



**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

[Audit Trail](#)

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

- CRF\_Sign

| Name          | Signature Meaning | Date  | Type | Action |
|---------------|-------------------|---|------|--------|
| Yanina Rivera | Approved          | Mar-19-2021 19:19:35 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, YaninaRivera, 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.

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (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:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45[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 |
|---------------|-------------------|---|------|--------|
| Yanina Rivera | Approved          | Mar-19-2021 19:19:35 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, YaninaRivera, 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-15-2021 13:51:58 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                |          |   |      |        |
|----------------|----------|---|------|--------|
| Carola Baldoni | Approved | Mar-09-2021 15:26:43 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|----------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, CarolaBaldoni, 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.

**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:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45

|                    |     |   |  |                                   |
|--------------------|-----|---|--|-----------------------------------|
| (b) (6)<br>(b) (6) | N/A | Mar-02-2021 18:39:39 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|--------------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                    |          |   |      |        |
|--------------------|----------|---|------|--------|
| (b) (6)<br>(b) (6) | Approved | Feb-18-2021 15:49:01 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|--------------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, (b) (6) 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-16-2021 19:49:32 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                    |          |   |      |        |
|--------------------|----------|---|------|--------|
| (b) (6)<br>(b) (6) | Approved | Feb-09-2021 17:29:55 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|--------------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, (b) (6) 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.

**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:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45

|                    |     |   |  |                                   |
|--------------------|-----|---|--|-----------------------------------|
| (b) (6)<br>(b) (6) | N/A | Feb-04-2021 17:18:56 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|--------------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                    |          |   |      |        |
|--------------------|----------|---|------|--------|
| (b) (6)<br>(b) (6) | Approved | Nov-05-2020 13:28:52 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|--------------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, (b) (6) 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)<br>(b) (6) | N/A | Nov-04-2020 16:11:12 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|--------------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                 |          |   |      |        |
|-----------------|----------|---|------|--------|
| Fernando Polack | Approved | Oct-23-2020 17:21:40 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|-----------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, FernandoPolack, 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.

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Oct-22-2020 08:29:08 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Oct-21-2020 18:40:20 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, (b) (6) 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.

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Select appropriate response - Protocol version*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020<br>19:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>30 JUN 2020 | Initial Entry |

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

| Date  | Location        | User                                 | Value                                 | Reason        |
|---|-----------------|--------------------------------------|---------------------------------------|---------------|
| Aug-18-2020<br>19:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**I. Consent Was:**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020<br>19:13:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Aug/18/2020 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** COHORT\_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1231**Subject No:** 12312080**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45[Back to Form](#)**1. Subject ID**

| Date   | Location        | User                    | Value                          | Reason                         |
|--|-----------------|-------------------------|--------------------------------|--------------------------------|
| Aug-18-2020 16:04:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>12312080 | Item copied from previous form |

**2. Birth Date:**

| Date   | Location        | User                    | Value                               | Reason           |
|--|-----------------|-------------------------|-------------------------------------|------------------|
| Aug-18-2020 16:04:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6) /1995 | Enrollment Entry |

**3. Sex:**

| Date   | Location        | User                                 | Value                      | Reason        |
|--|-----------------|--------------------------------------|----------------------------|---------------|
| Aug-18-2020 19:13:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>MALE | Initial Entry |

**4. Ethnicity:**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020 19:13:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>HISPANIC OR LATINO(A) OR OF SPANISH OR IGIN | Initial Entry |

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

| Date                 | Location        | User                                 | Value                       | Reason        |
|----------------------|-----------------|--------------------------------------|-----------------------------|---------------|
| Aug-18-2020 19:13:57 | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>WHITE | Initial Entry |



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|                                     |  |  |  |  |
|-------------------------------------|--|--|--|--|
| (UTC-03:00) City of<br>Buenos Aires |  |  |  |  |
|-------------------------------------|--|--|--|--|

**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L      **Form:** DATE OF VISIT - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1231      **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12312080      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Date of Visit*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020<br>19:14:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1.a*

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Inclusion Number:</b> 1<br><b>Criterion Description:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)<br><b>Criterion met?:</b> YES<br><b>Criterion ID:</b> IN01A00<br><b>For Pfizer use only):</b> | Initial Entry |

*1.a Inclusion Number:*

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45

|   |                 |                                      |                         |               |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |
|---|-----------------|--------------------------------------|-------------------------|---------------|

**1.a Criterion Description:**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | Initial Entry |

**1.a Criterion met?**

| Date  | Location        | User                                 | Value                     | Reason        |
|---|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.a Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>IN01A00 | Initial Entry |

**1.b**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |                        |  |  |                      |
|--|------------------------|--|--|----------------------|
| <p>Aug-18-2020<br/>19:14:26<br/>(UTC-03:00) City of Buenos Aires</p> | <p>ACV0PFEINFP6000</p> | <p>(b) (4), (b) (6)<br/>(b) (4), (b) (6)</p> | <p><b>Data Entry:</b><br/><b>Inclusion Number:</b> 2<br/><b>Criterion Description:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, life style considerations, and other study procedures<br/><b>Criterion met?</b> YES<br/>:<br/><b>Criterion ID:</b> IN02A00<br/><b>For Pfizer use only)</b><br/>:</p> | <p>Initial Entry</p> |
|--|------------------------|--|--|----------------------|

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45***1.b Inclusion Number:***

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>2 | Initial Entry |

***1.b Criterion Description:***

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures | Initial Entry |

***1.b Criterion met?***

| Date  | Location        | User                                 | Value                     | Reason        |
|---|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.b Criterion ID: (For Pfizer use only)***

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>IN02A00 | Initial Entry |

***1.c***

**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Inclusion Number:</b> 3<br><b>Criterion Description:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study<br><b>Criterion met?</b> YES<br>:<br><b>Criterion ID:</b> (For Pfizer use only)<br>:<br><b>Criterion ID:</b> (For Pfizer use only)<br>: | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45***I.c Inclusion Number:***

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

***I.c Criterion Description:***

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study | Initial Entry |

***I.c Criterion met?***

| Date  | Location        | User                                 | Value                     | Reason        |
|---|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***I.c Criterion ID: (For Pfizer use only)***

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>IN03A00 | Initial Entry |

***I.d***



**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Inclusion Number:</b> 4<br><b>Criterion Description:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol<br><b>Criterion met?</b> YES<br>:<br><b>Criterion ID:</b> (IN04A00)<br><b>For Pfizer use only)</b><br>: | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45**1.d Inclusion Number:**

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>4 | Initial Entry |

**1.d Criterion Description:**

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol | Initial Entry |

**1.d Criterion met?**

| Date  | Location        | User                                 | Value                     | Reason        |
|---|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.d Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>IN04A00 | Initial Entry |

**2.a**

**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History  
**Form Version:** 30-Jul-2020 21:27  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12312080  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 16:45

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Excl 1<br>usion<br>Num<br>ber:<br>Crite Other medical or p<br>rion sychiatric conditio<br>Desc n incl. recent (with<br>ripti in past year) or act<br>on: ive suicidal ideatio<br>n/behavior/lab abn<br>ormality that may<br>increase the risk of<br>study participation<br><br>Crite NO<br>rion<br>met?<br>:<br>Crite EX01A00<br>rion<br>ID: (<br>For<br>Pfize<br>r use<br>only)<br>: | Initial Entry |

**2.a Exclusion Number:**

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Criterion Description:**

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation | Initial Entry |

2.a Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.a Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX01A00 | Initial Entry |

2.b

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Exclu 2<br>sion N<br>umbe<br>r: | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <p><b>Criterion Description:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)</p> <p><b>Criterion Met?:</b> NO</p> <p><b>Criterion ID:</b> EX02A00</p> <p><b>Use Only:</b> (For Pfizer only):</p> |  |
|--|--|--|---|--|

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45**2.b Exclusion Number:**

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>2 | Initial Entry |

**2.b Criterion Description:**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) | Initial Entry |

**2.b Criterion met?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.b Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX02A00 | Initial Entry |

**2.c**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |                        |  |   |                      |
|--|------------------------|--|---|----------------------|
| <p>Aug-18-2020<br/>19:14:26<br/>(UTC-03:00) City of Buenos Aires</p> | <p>ACV0PFEINFP6000</p> | <p>(b) (4), (b) (6)<br/>(b) (4), (b) (6)</p> | <p><b>Data Entry:</b><br/><b>Exclusion Number:</b> 3<br/><b>Criterion Description:</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)<br/><b>Criterion met?</b> NO<br/>:<br/><b>Criterion ID:</b> EX03A00<br/><b>For Pfizer use only)</b><br/>:</p> | <p>Initial Entry</p> |
|--|------------------------|--|---|----------------------|

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45**2.c Exclusion Number:**

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

**2.c Criterion Description:**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) | Initial Entry |

**2.c Criterion met?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.c Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX03A00 | Initial Entry |

**2.d**



**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 4<br><b>Criterion Description:</b> Receipt of medications intended to prevent COVID-19<br><b>Criterion met?:</b> NO<br><b>Criterion ID: (For Pfizer use only):</b> EX04A00 | Initial Entry |

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

2.d Exclusion Number:

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>4 | Initial Entry |

2.d Criterion Description:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Receipt of medications in tended to prevent COVID -19 | Initial Entry |

2.d Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.d Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX04A00 | Initial Entry |

2.e

| Date        | Location        | User             | Value              | Reason        |
|-------------|-----------------|------------------|--------------------|---------------|
| Aug-18-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

19:14:26  
(UTC-03:00) City of Buenos Aires

(b) (4), (b) (6)

**Exclusion Number:** 8  
**Criterion Description:** Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination  
**Criterion met?:** NO  
**Criterion ID: (For Pfizer use only):** EX08A00

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

2.e Exclusion Number:

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>8 | Initial Entry |

2.e Criterion Description:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination | Initial Entry |

2.e Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.e Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX08A00 | Initial Entry |

2.f

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**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 10<br><b>Criterion Description:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection<br><b>Criterion met?</b> NO<br><b>Criterion ID:</b> EX10A00<br><b>Dose or Frequency:</b> (F or Pfizer only): | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

2.f Exclusion Number:

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>10 | Initial Entry |

2.f Criterion Description:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection | Initial Entry |

2.f Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.f Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX10A00 | Initial Entry |

2.g

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**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion 11</b><br><b>Number:</b><br><b>Criterion</b> Women who<br><b>Descriptio</b> are pregnant<br><b>n:</b> or breastfeed<br>ing<br><b>Criterion</b> NO<br><b>met?:</b><br><b>Criterion I</b> EX11A00<br><b>D: (For Pfi</b><br><b>zer use onl</b><br><b>y):</b> | Initial Entry |

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Header Text: C4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

2.g Exclusion Number:

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>11 | Initial Entry |

2.g Criterion Description:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Women who are pregnant or breastfeeding | Initial Entry |

2.g Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.g Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX11A00 | Initial Entry |

2.h

| Date        | Location        | User             | Value              | Reason        |
|-------------|-----------------|------------------|--------------------|---------------|
| Aug-18-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

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**Header Text:** C4591001

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

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**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

19:14:26  
(UTC-03:00) City of Buenos Aires

(b) (4), (b) (6)

**Exclusion 12 Number:**  
**Criterion Description:** Previous vaccination with any coronavirus vaccine  
**Criterion met?:** NO  
**Criterion ID: (For Pfizer use only):** EX12A00

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

2.h Exclusion Number:

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>12 | Initial Entry |

2.h Criterion Description:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Previous vaccination with any coronavirus vaccine | Initial Entry |

2.h Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.h Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX12A00 | Initial Entry |

2.i

| Date        | Location        | User             | Value              | Reason        |
|-------------|-----------------|------------------|--------------------|---------------|
| Aug-18-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

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**Header Text:** C4591001

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**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

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(UTC-03:00) City of Buenos Aires

(b) (4), (b) (6)

**Exclusion Number:** 13

**Criteria Description:** Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids

**Criteria Met?:** NO

**Criteria ID:** EX13A01  
**(For Pfizer use only):**

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Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

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Subject Initials: ---

Generated By: (b) (4)

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2.i Exclusion Number:

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>13 | Initial Entry |

2.i Criterion Description:

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids | Initial Entry |

2.i Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.i Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX13A01 | Initial Entry |

2.j

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

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**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |                        |  |   |                      |
|--|------------------------|--|---|----------------------|
| <p>Aug-18-2020<br/>19:14:26<br/>(UTC-03:00) City of Buenos Aires</p> | <p>ACV0PFEINFP6000</p> | <p>(b) (4), (b) (6)<br/>(b) (4), (b) (6)</p> | <p><b>Data Entry:</b><br/><b>Exclusion Number:</b> 15<br/><b>Criterion Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study<br/><b>Criterion met?</b> NO<br/><b>Criterion ID:</b> EX14A01<br/><b>Dose or Frequency:</b> (F or Pfizer use only):</p> | <p>Initial Entry</p> |
|--|------------------------|--|---|----------------------|

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

2.j Exclusion Number:

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>15 | Initial Entry |

2.j Criterion Description:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study | Initial Entry |

2.j Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.j Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX14A01 | Initial Entry |

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

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**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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2.k

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 16<br><b>Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation<br><b>Criterion met?:</b> NO<br><b>Criterion ID:</b> EX15A01<br><b>D: (For Pfizer use only):</b> | Initial Entry |

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Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

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2.k Exclusion Number:

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>16 | Initial Entry |

2.k Criterion Description:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation | Initial Entry |

2.k Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.k Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX15A01 | Initial Entry |

2.l

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

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**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |                        |  |  |                      |
|--|------------------------|--|--|----------------------|
| <p>Aug-18-2020<br/>19:14:26<br/>(UTC-03:00) City of Buenos Aires</p> | <p>ACV0PFEINFP6000</p> | <p>(b) (4), (b) (6)<br/>(b) (4), (b) (6)</p> | <p><b>Data Entry:</b><br/><b>Exclusion Number:</b> 17<br/><b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles<br/><b>Criterion ID:</b> NO<br/><b>For Pfizer use only</b></p> | <p>Initial Entry</p> |
|--|------------------------|--|--|----------------------|

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**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45**2.1 Exclusion Number:**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>17 | Initial Entry |

**2.1 Criterion Description:**

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Previous participation in other studies involving study intervention containing lipid nanoparticles | Initial Entry |

**2.1 Criterion met?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.1 Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX16A01 | Initial Entry |

**2.m**

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

**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |                        |  |  |                      |
|--|------------------------|--|--|----------------------|
| <p>Aug-18-2020<br/>19:14:26<br/>(UTC-03:00) City of Buenos Aires</p> | <p>ACV0PFEINFP6000</p> | <p>(b) (4), (b) (6)<br/>(b) (4), (b) (6)</p> | <p><b>Data Entry:</b><br/><b>Excl</b> 22<br/><b>usio</b><br/><b>n Nu</b><br/><b>mbe</b><br/><b>r:</b><br/><b>Crit</b> Investigator site st<br/><b>erio</b> aff or Pfizer empl<br/><b>n De</b> oyees directly inv<br/><b>scrip</b> olved in the condu<br/><b>tion:</b> ct of the study, sit<br/>e staff otherwise s<br/>upervised by the i<br/>nvestigator, and th<br/>eir respective fami<br/>ly members<br/><b>Crit</b> NO<br/><b>erio</b><br/><b>n me</b><br/><b>t?:</b><br/><b>Crit</b> EX21A01<br/><b>erio</b><br/><b>n ID</b><br/><b>: (Fo</b><br/><b>r Pfi</b><br/><b>zer u</b><br/><b>se on</b><br/><b>ly):</b></p> | <p>Initial Entry</p> |
|--|------------------------|--|--|----------------------|

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

2.m Exclusion Number:

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>22 | Initial Entry |

2.m Criterion Description:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members | Initial Entry |

2.m Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.m Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020<br>19:14:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX21A01 | Initial Entry |

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020<br>19:14:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-18-2020 19:14:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date  | Location        | User                                 | Value                           | Reason        |
|---|-----------------|--------------------------------------|---------------------------------|---------------|
| Aug-18-2020<br>19:14:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12312080**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 16:45[Back to Form](#)**1.a**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Aug-18-2020 19:14:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH Number: 1<br>Medical History Term: Smoking<br>Start Date: May/1/2008<br>Ongoing: YES | Initial Entry |

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

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Aug-18-2020 19:14:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

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

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-18-2020 19:14:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Smoking | Initial Entry |

**1.a Start Date:**

| Date   | Location        | User                                 | Value                            | Reason        |
|--|-----------------|--------------------------------------|----------------------------------|---------------|
| Aug-18-2020 19:14:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>May/1/2008 | Initial Entry |

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

|              |  |  |  |  |
|--------------|--|--|--|--|
| Buenos Aires |  |  |  |  |
|--------------|--|--|--|--|

***1.a Ongoing:***

| Date   | Location        | User                                 | Value                     | Reason        |
|--|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-18-2020 19:14:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.b***

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Aug-18-2020 19:15:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b><br><b>Medical History Term:</b> Seasonal allergy<br><b>Start Date:</b> Apr/1/2010<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Aug-18-2020 19:15:19<br>(UTC-03:00) City of Buenos Aires | 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-18-2020 19:15:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Seasonal allergy | Initial Entry |

***1.b Start Date:***

| Date   | Location        | User                                 | Value                            | Reason        |
|--|-----------------|--------------------------------------|----------------------------------|---------------|
| Aug-18-2020 19:15:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Apr/1/2010 | Initial Entry |

***1.b Ongoing:***

| Date   | Location        | User                                 | Value                     | Reason        |
|--|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-18-2020 19:15:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Date:**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**2. Weight:**

| Date  | Location        | User                                 | Value                       | Reason        |
|---|-----------------|--------------------------------------|-----------------------------|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>107.0 | Initial Entry |

**3. Unit:**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>kg | Initial Entry |

**4. Height:**

| Date  | Location        | User                                 | Value                       | Reason        |
|---|-----------------|--------------------------------------|-----------------------------|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>178.0 | Initial Entry |

**5. Unit:**

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

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1231**Subject No:** 12312080**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45

|  |                 |                                      |                          |               |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>cm | Initial Entry |
|--|-----------------|--------------------------------------|--------------------------|---------------|

**6. Body Mass Index:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-18-2020 19:15:40<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>33.8 | Initial Entry |

**7.a**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b><br><b>Temperature:</b> 36.2<br><b>Temperature C</b><br><b>Unit:</b><br><b>Temperature ORAL C</b><br><b>Location:: AVITY</b> | Initial Entry |

**7.a Record Identifier:**

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**7.a Temperature:**

| Date                    | Location        | User                                 | Value                      | Reason        |
|-------------------------|-----------------|--------------------------------------|----------------------------|---------------|
| Aug-18-2020<br>19:15:40 | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>36.2 | Initial Entry |

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

(UTC-03:00) City of Buenos Aires

**7.a Unit:**

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

**7.a Temperature Location:**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020<br>19:15:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Randomization Date :**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020<br>19:15:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**2. Randomization Number:**

| Date  | Location        | User                                 | Value                       | Reason        |
|---|-----------------|--------------------------------------|-----------------------------|---------------|
| Aug-18-2020<br>19:15:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>55186 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-18-2020 19:16:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Aug-18-2020 19:16:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                                 | Value  | Reason   |
|--|-----------------|--------------------------------------|--|--|
| Aug-19-2020 15:09:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Deleted                                 | Close Auto Query   |
| Aug-18-2020 19:16:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Candidate                               | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-18-2020 19:16:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection: | Initial Entry  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12312080

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

|  |  |  |             |  |
|--|--|--|-------------|--|
|  |  |  | Aug/18/2020 |  |
|--|--|--|-------------|--|

5.a

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020<br>15:09:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BPHYH4 | Initial Entry |

5.a Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020<br>15:09:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPHYH4 | Initial Entry |

5.b

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020<br>15:09:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BPHYH5 | Initial Entry |

5.b Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020<br>15:09:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPHYH5 | Initial Entry |

5.c

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

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**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Aug-22-2020<br>12:03:17 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BHY45F | Initial Entry |
|---|-----------------|---------------------|--|---------------|

**5.c Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-22-2020<br>12:03:17 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BHY45F | Initial Entry |

**5.d**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Aug-22-2020<br>12:03:23 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BHY45G | Initial Entry |

**5.d Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-22-2020<br>12:03:23 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BHY45G | Initial Entry |

**5.e**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Aug-22-2020<br>12:03:29 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BHY45H | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**5.e Sample ID**

| <b>Date</b>   | <b>Location</b> | <b>User</b>         | <b>Value</b>                 | <b>Reason</b> |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-22-2020<br>12:03:29 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BHY45H | 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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-18-2020 19:16:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Aug-18-2020 19:16:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason   |
|--|-----------------|---------------------------|--------------------|--|
| Aug-22-2020 09:45:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed    | Close Auto Query   |
| Aug-19-2020 15:46:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened    | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-18-2020 19:16:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (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:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12312080 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

|   |                 |                                      |   |  |
|---|-----------------|--------------------------------------|---|--|
|   |                 |                                      |   | entered. Please review and correct as appropriate. |
| Aug-18-2020<br>19:16:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/18/2020 | Initial Entry                                      |

**5.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Aug-22-2020<br>09:45:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BHWTP3 | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-22-2020<br>09:45:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BHWTP3 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User                                 | Value                                   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/18/2020 17:35 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312080

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

|              |  |  |  |  |
|--------------|--|--|--|--|
| Buenos Aires |  |  |  |  |
|--------------|--|--|--|--|

6. Body Side:

| Date   | Location        | User                                 | Value                      | Reason        |
|--|-----------------|--------------------------------------|----------------------------|---------------|
| Aug-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

7. Route:

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Aug-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OBSERVATION 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-18-2020 19:16:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Select appropriate response - Reactogenicity diary collection*

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020<br>19:16:30<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO - REACTOGENICIT<br>Y E-DIARY NOT COLL<br>ECTED FOR THIS SUBJ<br>ECT | Initial Entry |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Date of Visit*

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-08-2020 17:10:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/8/2020 | Initial Entry |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**I. Date:**

| Date   | Location        | User             | Value                            | Reason        |
|--|-----------------|------------------|----------------------------------|---------------|
| Sep-08-2020 17:10:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sep/8/2020 | Initial Entry |

**2.a**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Sep-08-2020 17:10:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Record Identifier:<br>Temperature: 36.5<br>Temperature Unit:<br>Temperature Location: ORAL CAVITY | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User             | Value                   | Reason        |
|--|-----------------|------------------|-------------------------|---------------|
| Sep-08-2020 17:10:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date   | Location        | User             | Value                      | Reason        |
|--|-----------------|------------------|----------------------------|---------------|
| Sep-08-2020 17:10:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>36.5 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |  |                  |  |
|--|--|------------------|--|
|  |  | (b) (4), (b) (6) |  |
|--|--|------------------|--|

**2.a Unit:**

| Date   | Location        | User             | Value                   | Reason        |
|--|-----------------|------------------|-------------------------|---------------|
| Sep-08-2020 17:10:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

**2.a Temperature Location:**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Sep-08-2020 17:10:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-08-2020 17:11:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-08-2020 17:11:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Sep-08-2020 18:36:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Sep-08-2020 17:11:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-08-2020 17:11:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b)<br>(4),<br>(b)<br>(6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Sep/8/2020 | Initial Entry  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**5.a**

| Date  | Location        | User                    | Value                                   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Sep-08-2020<br>18:36:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br>Sample ID: BP2DDD | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User                    | Value                        | Reason        |
|---|-----------------|-------------------------|------------------------------|---------------|
| Sep-08-2020<br>18:36:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br>BP2DDD | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                 | Value                                 | Reason        |
|--|-----------------|----------------------|---------------------------------------|---------------|
| Sep-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                 | Value                           | Reason        |
|--|-----------------|----------------------|---------------------------------|---------------|
| Sep-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Sep-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sep/8/2020 14:55 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                 | Value                                | Reason        |
|--|-----------------|----------------------|--------------------------------------|---------------|
| Sep-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312080

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

|              |  |  |  |  |
|--------------|--|--|--|--|
| Buenos Aires |  |  |  |  |
|--------------|--|--|--|--|

6. Body Side:

| Date   | Location        | User             | Value                      | Reason        |
|--|-----------------|------------------|----------------------------|---------------|
| Sep-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

7. Route:

| Date   | Location        | User                 | Value                               | Reason        |
|--|-----------------|----------------------|-------------------------------------|---------------|
| Sep-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date   | Location        | User                 | Value   | Reason        |
|--|-----------------|----------------------|---|---------------|
| Sep-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OBSERVATION 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-08-2020 17:11:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Date of Visit**

| Date  | Location        | User                                 | Value                            | Reason   |
|---|-----------------|--------------------------------------|----------------------------------|--|
| Oct-15-2020<br>02:09:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)                  | Query 1: Closed                  | Response satisfies query   |
| Oct-14-2020<br>10:28:33<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Query 1: Answered                | EOT form completed   |
| Oct-13-2020<br>09:03:21<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)                     | Query 1: Opened                  | DM: Patient completed the treatment phase and reached at Visit 3. Kindly consider to update EOT form with matching V3 date or else clarify. Thank you. |
| Oct-06-2020<br>16:24:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)                     | <b>Data Entry:</b><br>Oct/6/2020 | Initial Entry  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-06-2020 16:24:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-06-2020 16:24:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                           | Value  | Reason   |
|--|-----------------|--------------------------------|--|--|
| Oct-06-2020 18:40:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)      | Query 1: Deleted   | Close Auto Query   |
| Oct-06-2020 16:24:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)      | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-06-2020 16:24:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted] | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/6/2020 | Initial Entry  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-06-2020 18:40:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BNV61J | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-06-2020 18:40:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BNV61J | Initial Entry |

**5.b**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-06-2020 19:33:30<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BNV614 | Initial Entry |

**5.b Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-06-2020 19:33:30<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BNV614 | Initial Entry |

**5.c**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-07-2020 11:47:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BP1VRC | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**5.c Sample ID**

| <b>Date</b>  | <b>Location</b> | <b>User</b>         | <b>Value</b>                 | <b>Reason</b> |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-07-2020 11:47:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BP1VRC | Initial Entry |



**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Date of Visit*

| Date   | Location        | User                                 | Value                             | Reason        |
|--|-----------------|--------------------------------------|-----------------------------------|---------------|
| Mar-15-2021 13:51:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Mar/15/2021 | Initial Entry |

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-15-2021 13:52:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Mar-15-2021 13:52:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason   |
|--|-----------------|---------------------------|--------------------|--|
| Mar-16-2021 09:11:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed    | Close Auto Query   |
| Mar-16-2021 08:31:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened    | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-15-2021 13:52:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: V4\_MONTH6\_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312080

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

|   |                 |                                      |   |  |
|---|-----------------|--------------------------------------|---|--|
|   |                 |                                      |   | entered. Please review and correct as appropriate. |
| Mar-15-2021<br>13:52:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Mar/15/2021 | Initial Entry                                      |

5.a

| Date  | Location        | User   | Value                                   | Reason        |
|---|-----------------|--|---|---------------|
| Mar-16-2021<br>09:11:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted]<br>[Redacted] | <b>Data Entry:</b><br>Sample ID: BRYHGX | Initial Entry |

5.a Sample ID

| Date  | Location        | User   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Mar-16-2021<br>09:11:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted]<br>[Redacted] | <b>Data Entry:</b><br>BRYHGX | Initial Entry |

5.b

| Date  | Location        | User                           | Value                                   | Reason        |
|---|-----------------|--------------------------------|---|---------------|
| Mar-16-2021<br>09:18:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted] | <b>Data Entry:</b><br>Sample ID: BRYHJM | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**5.b Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Mar-16-2021<br>09:18:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BRYHJM | Initial Entry |

**5.c**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Mar-16-2021<br>09:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPT6CP | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Mar-16-2021<br>09:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BPT6CP | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

| Date   | Location        | User                                 | Value                            | Reason        |
|--|-----------------|--------------------------------------|----------------------------------|---------------|
| Oct-14-2020 10:28:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/6/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-14-2020 10:28:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date   | Location        | User                                 | Value                           | Reason        |
|--|-----------------|--------------------------------------|---------------------------------|---------------|
| Oct-14-2020 10:28:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Date of Visit*

| Date  | Location        | User                      | Value                            | Reason        |
|---|-----------------|---------------------------|----------------------------------|---------------|
| Feb-04-2021 17:18:56<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b)<br>(4),<br>(b)<br>(6) | <b>Data Entry:</b><br>Feb/4/2021 | Initial Entry |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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***I. Consent Was:***

| Date  | Location        | User                      | Value   | Reason        |
|---|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:19:06<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b)<br>(4),<br>(b)<br>(6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtai<br>ned<br><br>Feb/4/2021 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-04-2021 17:19:18<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-04-2021 17:19:18<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                              | Value              | Reason   |
|---|-----------------|-----------------------------------|--------------------|--|
| Feb-06-2021 08:47:05<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)         | Query 1: Closed    | Close Auto Query   |
| Feb-04-2021 18:12:14<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[REDACTED] | Query 1: Opened    | 'Sample Collected?' is<br>Yes, however no<br>barcodes are<br>entered. Please<br>review and<br>correct as<br>appropriate. |
| Feb-04-2021 17:19:18<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)         | Query 1: Candidate | 'Sample Collected?' is<br>Yes, however no<br>barcodes are<br>entered. Please   |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |                 |                     |  |                                    |
|--|-----------------|---------------------|--|------------------------------------|
|  |                 |                     |  | review and correct as appropriate. |
| Feb-04-2021 17:19:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Feb/4/2021 | Initial Entry                      |

**5.a**

| Date   | Location        | User                             | Value  | Reason        |
|--|-----------------|----------------------------------|--|---------------|
| Feb-06-2021 08:47:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BLBGJB | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                             | Value                        | Reason        |
|--|-----------------|----------------------------------|------------------------------|---------------|
| Feb-06-2021 08:47:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br>BLBGJB | Initial Entry |

**5.b**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Feb-06-2021 09:35:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BLBGJ3 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**5.b Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Feb-06-2021<br>09:35:15<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BLBGJ3 | Initial Entry |

**5.c**

| Date  | Location        | User             | Value                                   | Reason        |
|---|-----------------|------------------|---|---------------|
| Feb-06-2021 10:00:00<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID: BPWD53 | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Feb-06-2021 10:00:00<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BPWD53 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-05-2021 10:16:47<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-05-2021 10:16:47<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value  | Reason   |
|---|-----------------|---------------------------|--|--|
| Feb-05-2021 16:04:57<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Feb-05-2021 10:16:47<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is<br>Yes, however no<br>barcodes are<br>entered. Please<br>review and<br>correct as<br>appropriate. |
| Feb-05-2021 10:16:47<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b)<br>(4),<br>(b)<br>(6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Feb/4/2021 | Initial Entry  |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**5.a**

| Date  | Location        | User                                   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Feb-05-2021 16:04:57<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Agustin<br>Morato<br>Cabral<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BHXGRY | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Feb-05-2021 16:04:57<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Agustin<br>Morato<br>Cabral<br>(b) (4) | <b>Data Entry:</b><br>BHXGRY | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/16/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Date of Visit**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Feb-16-2021 19:49:31<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Feb/16/2021 | Initial Entry |

**3. COVID-19 Surveillance Visit:**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Feb-16-2021 19:49:31<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>SSWAB_WEEK2 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/16/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1231**Subject No:** 12312080**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-16-2021 19:49:42<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                                 | Value                            | Reason        |
|---|-----------------|--------------------------------------|----------------------------------|---------------|
| Feb-16-2021 19:49:42<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                 | Value   | Reason  |
|---|-----------------|--------------------------------------|---|---|
| Feb-17-2021 12:12:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Deleted  | Close Auto<br>Query   |
| Feb-16-2021 19:49:42<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Candidate  | 'Sample<br>Collected?' is<br>Yes, however no<br>barcodes are<br>entered. Please<br>review and<br>correct as<br>appropriate. |
| Feb-16-2021 19:49:42<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Feb/16/2021 | Initial Entry   |

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/16/2021

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**5.a**

| Date  | Location        | User                                   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Feb-17-2021 12:12:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Agustin<br>Morato<br>Cabral<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BP87WB | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Feb-17-2021 12:12:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Agustin<br>Morato<br>Cabral<br>(b) (4) | <b>Data Entry:</b><br>BP87WB | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/26/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Date of Visit**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Mar-02-2021<br>18:39:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Feb/26/2021 | Initial Entry |

**3. COVID-19 Surveillance Visit:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Mar-02-2021<br>18:39:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SSWAB_WEEK4 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)



**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Feb/26/2021

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-02-2021 18:39:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Mar-02-2021 18:39:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason   |
|--|-----------------|---------------------------|--------------------|--|
| Mar-03-2021 09:29:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed    | Close Auto Query   |
| Mar-03-2021 08:28:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened    | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-02-2021 18:39:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no   |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001  
**Visit:** V202\_SURVEIL\_SWAB 2 -  
 Unscheduled Visit on Feb/26/2021  
**Form Version:** 10-Oct-2020 15:57  
**Site No:** 1231  
**Subject No:** 12312080  
**Generated By:** (b) (4)  
**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
 eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
 Cosme Argerich  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 16:45

|   |                 |                     |   |   |
|---|-----------------|---------------------|---|---|
| Buenos Aires  |                 |                     |   | barcodes are entered. Please review and correct as appropriate. |
| Mar-02-2021<br>18:39:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Feb/26/2021 | Initial Entry   |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Mar-03-2021<br>09:29:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BP1Z44 | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Mar-03-2021<br>09:29:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP1Z44 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/08/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Date of Visit**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Mar-09-2021<br>14:15:16<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/8/2021 | Initial Entry |

**3. COVID-19 Surveillance Visit:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Mar-09-2021<br>14:15:16<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SSWAB_WEEK6 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/08/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1231**Subject No:** 12312080**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-09-2021 14:15:34<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Mar-09-2021<br>14:15:34<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value  | Reason  |
|--|-----------------|---------------------------|--|---|
| Mar-09-2021<br>14:15:49<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted                                 | Close Auto<br>Query   |
| Mar-09-2021<br>14:15:34<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate                               | 'Sample<br>Collected?' is<br>Yes, however no<br>barcodes are<br>entered. Please<br>review and<br>correct as<br>appropriate. |
| Mar-09-2021<br>14:15:34<br>(UTC-03:00) City of                 | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection: | Initial Entry   |

**Header Text:** C4591001  
**Visit:** V202\_SURVEIL\_SWAB 3 -  
 Unscheduled Visit on Mar/08/2021  
**Form Version:** 10-Oct-2020 15:57  
**Site No:** 1231  
**Subject No:** 12312080  
**Generated By:** (b) (4)  
**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
 eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
 Cosme Argerich  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 16:45

|              |  |  |            |  |
|--------------|--|--|------------|--|
| Buenos Aires |  |  | Mar/8/2021 |  |
|--------------|--|--|------------|--|

**5.a**

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-09-2021<br>14:15:49<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BR22D6 | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Mar-09-2021<br>14:15:49<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR22D6 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (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, Locked, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Date of Visit*

| Date  | Location        | User                      | Value                            | Reason        |
|---|-----------------|---------------------------|----------------------------------|---------------|
| Mar-08-2021 15:39:53<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b)<br>(4),<br>(b)<br>(6) | <b>Data Entry:</b><br>Mar/8/2021 | Initial Entry |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.  
Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

| Date  | Location        | User                      | Value  | Reason        |
|---|-----------------|---------------------------|--|---------------|
| Mar-08-2021 15:40:05<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b)<br>(4),<br>(b)<br>(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 |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

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

**Form Status:**

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312080

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | 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                       |
|--|---|---------------------------|--|------------------------------|
| Oct-23-2020 12:34:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)  | Query 2: Closed                              | Discrepancy has been closed. |
| Oct-23-2020 10:41:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | auto query<br>(autoquery) | Query 2: Answered                            | Transcription Error          |
| Oct-23-2020 10:41:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)          | <b>Data Entry:</b><br>: left in guinal adeno | Transcription Error          |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|  |   |                            | pathy   |   |
|--|---|----------------------------|---|---|
| Oct-23-2020<br>02:19:56<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 2: Opened                                   | Special Characters: Verbatim Term contains embedded non-compliant characters. |
| Oct-23-2020<br>01:01:14<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 1: Closed                                   | Discrepancy has been closed.  |
| Oct-22-2020<br>17:27:36<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | auto query (autoquery)     | Query 1: Answered                                 | Transcription Error   |
| Oct-22-2020<br>17:27:36<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | Adolfo Gonzalez<br>(b) (4) | <b>Data Entry</b><br>: left in guinal adeno pathy | Transcription Error   |
| Oct-22-2020<br>09:25:52<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 1: Opened                                   | Special Characters: Verbatim Term contains embedded non-compliant characters. |
| Oct-22-2020<br>08:29:08  | ACV0PFEINFP6000                           | (b) (4), (b) (6)           | <b>Data Entry</b>                                 | Initial Entry   |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|   |  |  |  |  |
|---|--|--|--|--|
| (UTC-03:00)<br>City of<br>Buenos<br>Aires |  |  |  | i<br>Left i<br>nguinal<br>ade<br>nopat<br>hy |
|---|--|--|--|--|

**4. Start Date Time:**

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/20/2020 10:30 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                | Value  | Reason          |
|---|-----------------|---------------------|--|-----------------|
| Nov-04-2020<br>16:11:12 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Nov/3/2020 09:00 | New Information |
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>YES                                      | Initial Entry   |

**6. Toxicity Grade:**

| Date  | Location        | User                | Value                   | Reason        |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | 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  |
|---|-----------------|------------------------------|--|---|
| Oct-26-2020<br>14:22:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Marjorie Buonanno<br>(b) (4) | Query 1: Closed  | Response satisfies query                                    |
| Oct-26-2020<br>10:54:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 1: Answered  | To date, the etiology of the event remains unknown          |
| Oct-23-2020<br>15:53:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Marjorie Buonanno<br>(b) (4) | Query 1: Opened  | GPD Clin:<br>Please provide PI opinion of possible etiology |
| Oct-22-2020<br>08:29:08<br>(UTC-03:00) City of              | ACV0PFEINFP6000 | (b) (4), (b) (6)             | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study t | Initial Entry   |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312080

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

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

|              |  |  |   |
|--------------|--|--|---|
| Buenos Aires |  |  | reatment(s), this event i<br>s due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>unknown |
|--------------|--|--|---|

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

| Date   | Location        | User                              | Value                                | Reason        |
|--|-----------------|-----------------------------------|--------------------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[Redacted] | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

| Date   | Location        | User                              | Value                    | Reason        |
|--|-----------------|-----------------------------------|--------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[Redacted] | <b>Data Entry:</b><br>NO | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User                              | Value                    | Reason        |
|--|-----------------|-----------------------------------|--------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[Redacted] | <b>Data Entry:</b><br>NO | Initial Entry |

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

| Date  | Location        | User                      | Value           | Reason           |
|---|-----------------|---------------------------|-----------------|------------------|
| Nov-04-2020<br>17:24:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed | Close Auto Query |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12312080**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45

|   |                 |                            |  |   |
|---|-----------------|----------------------------|--|---|
| Nov-04-2020<br>17:24:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Adolfo Gonzalez<br>(b) (4) | <b>Data Entry:</b><br>RECOVERED/RESOLVED         | New Information   |
| Nov-04-2020<br>16:11:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Opened                                  | For AE left inguinal adenopathy: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present. |
| Oct-22-2020<br>08:29:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)           | <b>Data Entry:</b><br>NOT RECOVERED/NOT RESOLVED | Initial Entry   |

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-22-2020 08:29:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Date Treatment Unblinded :**

| Date   | Location        | User             | Value                            | Reason        |
|--|-----------------|------------------|----------------------------------|---------------|
| Mar-08-2021 15:39:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Mar/8/2021 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Mar-08-2021 15:39:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Subject Status**

| Date   | Location        | User                    | Value                                     | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-14-2020 10:28:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Aug-18-2020 19:15:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Aug-18-2020 19:14:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry |

**2. Subject Status Date**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-14-2020 10:28:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/6/2020  | Initial Entry |
| Aug-18-2020 19:15:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |
| Aug-18-2020 19:14:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

090177e196ae2e5b\Final\Final On: 01-Apr-2021 03:10 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12312080

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Casebook Signature*

| Date   | Location        | User             | Value                                      | Reason        |
|--|-----------------|------------------|--|---------------|
| Oct-21-2020<br>18:40:09<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |