

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[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 |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/22/2020 |
|----|--------------|--|

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [12313184] |
| 2. | Birth Date: | (b) (6)/1971 |
| 3. | Sex: | MALE |
| 4. | Ethnicity: | HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Aug/22/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

[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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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

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

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Header Text: C4591001

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Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

| | | |
|-----|-------------------------------------|---|
| 2.g | Exclusion Number: | 11 |
| | Criterion Description: | Women who are pregnant or breastfeeding |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX11A00 |
| 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 |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

| | | |
|-----|-------------------------------------|---|
| 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 |
| 2.l | 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: 12313184

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 20:20

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Aug/22/2020 |
| 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: 12313184

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 20:20

[Form Comments](#)

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|-------------------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Cholecystectomy] |
| | Start Date: | Jan/1/2016 |
| | Ongoing: | NO End Date: Jan/1/2016 |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Aug/22/2020 |
| 2. | Weight: | [82.5] |
| 3. | Unit: | kg |
| 4. | Height: | [183.0] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [24.6] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [36.3] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

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 20:20

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Aug/22/2020 |
| 2. | Randomization Number: | [62043] |
| 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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Aug/22/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BHY6NB] |
| 5.b | Sample ID | [BHY6NC] |
| 5.c | Sample ID | [BHY6ND] |
| 5.d | Sample ID | [BJ49YR] |
| 5.e | Sample ID | [BJ49YS] |
| 5.f | Sample ID | [BJ49YT] |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/22/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP2CGJ] |
|-----|-----------|----------|

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

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 20:20

[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/22/2020 14:35 |
| 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: 12313184

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 20:20

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | Sep/10/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/10/2020 |
|----|-------|-------------|

Vital Signs Details

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/10/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP242K] |
|-----|-----------|----------|

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

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 20:20

[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/10/2020 17:20 |
| 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 |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | Oct/14/2020 |
| 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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Oct/14/2020 |
| 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 | [BP1NM6] |
| 5.b | Sample ID | [BRXS61] |
| 5.c | Sample ID | [BRXS6X] |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Mar/16/2021 |
| 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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Mar/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 | [BRMRNZ] |
| 5.b | Sample ID | [BRZ2X1] |
| 5.c | Sample ID | [BRZ2XH] |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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 Version: 28-Mar-2021 02:35

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

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 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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? | |
|----|--|--|

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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: 12313184

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 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

Unplanned Assessments

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

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Oct/14/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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 - **Form:** DATE OF VISIT - REPEAT SWAB
New Unscheduled Visit

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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 - **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
New Unscheduled Visit 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: 12313184 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

Vital Signs

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

Vital Signs Details

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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? | |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:20

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

Contact Outcome

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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: 12313184 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 20:20

Date of Visit

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

Informed Consent - Asymptomatic Surveillance

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

| | |
|---|--|
| Header Text: C4591001 | |
| Visit: V201_SURVEIL_CONSENT - Unscheduled | Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB |
| Form Version: 22-Apr-2020 21:03 | Form Status: Not Started |
| Site No: 1231 | Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich |
| Subject No: 12313184 | Subject Initials: --- |
| Generated By: (b) (4) | Generated Time (GMT): 29-Mar-2021 20:20 |

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

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

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Mar/11/2021 |
| 2. | Erroneous Visit | |

Header Text: C4591001

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

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: 12313184 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: 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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|------------------------------|-------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | right carpal tunnel syndrome | Oct/15/2020 20:00 | NO End Date Time: Feb/19/2021 12:00 | Repeating Pages |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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 20:20

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

| | | |
|----|--|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [right carpal tunnel syndrome] |
| 4. | Start Date Time: | Oct/15/2020 20:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/19/2021 12:00 |
| 6. | Toxicity Grade: | 2 |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12313184**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**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 20:20

| | | |
|-----|---|--|
| 7. | <p>Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p> | <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p> |
| 8. | <p>Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.</p> | NO |
| 9. | <p>Is this event related to study treatment:</p> | <p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [unknown]</p> |
| 10. | <p>Latest Action Taken with Study Treatment:</p> | NOT APPLICABLE |

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | |
|-----|--|--------------------|
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2021112498] |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1231

Subject No: 12313184

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 20:20

[Back to Form](#)

Medication Error

| | | |
|-----|---|-----|
| 1. | Category: | |
| 2. | Medication Error (Type of Medication Error): | [] |
| 3. | Start Date: | // |
| 4. | Is the medication error still ongoing? | |
| 5. | Latest Action Taken with Study Treatment: | |
| 6. | Was a Concomitant Medication given? | |
| 7. | Was a Non-Drug Treatment given? | |
| 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 | [] |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[Back to Form](#)

Concomitant Medications

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

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 20:20

[Back to Form](#)

Concomitant Medications

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

[Back to Form](#)

Radiation Treatment

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

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[Back to Form](#)

| | | |
|----|----------------------|----|
| 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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| 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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

Booster Dose Trigger Form

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Mar/11/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

Withdrawal Of Consent

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

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Oct/14/2020 |

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-----------------|-------------------|--|------|--------|
| Fernando Polack | Approved | Mar-17-2021 20:09:03 (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: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

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 20:20

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| Item | Date | User | Comment |
|------|--|--------------------------------|----------------|
| Form | Feb-04-2021 10:41:26 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) [Redacted] | |
| Form | Aug-22-2020 15:19:44 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[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 |
|-----------------|-------------------|--|------|--------|
| Fernando Polack | Approved | Mar-17-2021 20:09:03 (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.

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Mar-11-2021 16:26:12 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|--|------|--------|
| Tatiana Estrada | Approved | Feb-22-2021 15:55:17 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|-----------------|----------|--|------|--------|

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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:** 12313184**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:20**Affidavit:**

By my dated signature below, I, Tatiana Estrada, 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-20-2021 16:22:59 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|---|

Affidavit:

N/A

| | | | | |
|---------|----------|--|------|--------|
| (b) (6) | Approved | Feb-16-2021 13:35:45 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|---------|-----|--|--|---|
| (b) (6) | N/A | Feb-13-2021 10:33:41 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|---|

Affidavit:

N/A

| | | | | |
|---------|----------|--|------|--------|
| (b) (6) | Approved | Feb-09-2021 17:29:39 (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-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|---|

Affidavit:

N/A

| | | | | |
|---------|----------|--|------|--------|
| (b) (6) | Approved | Oct-22-2020 15:34:32 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|--|------|--------|

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12313184

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 20:20

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Aug-22-2020 15:18:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 30 JUN 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:18:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORT S | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[Back to Form](#)

1. Consent Was:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:18:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Cons ent Obtained Aug/22/2020 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12313184

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 20:20

[Back to Form](#)

1. Subject ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------|--------------------------------------|
| Aug-22-2020 13:32:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12313184 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|------------------------------------|---------------------|
| Aug-22-2020 13:32:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1971 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------|---------------|
| Aug-22-2020 15:18:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: MALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:18:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HISPANIC OR LAT INO(A) OR OF SPA NISH ORIGIN | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12313184

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 20:20

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------|---------------|
| Aug-22-2020 15:18:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Aug-22-2020 15:19:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/22/2020 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[Back to Form](#)

1.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 1 usio n N um ber: Crit Male or femal erio e participants n D between the ag escr es of 18 and 5 ipti 5 years, inclusi on: ve, 65 and 85 years, inclusiv e, or 18 and 85 years, inclusiv e, at randomiz ation (depende nt upon study stage) Crit YES erio n m et?: | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|--|--|--|--|
| | | | Crit IN01A00 erion I D: (For Pfizer er u se o nly) : | |
|--|--|--|--|--|

1.a Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

1.a Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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 |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

1.a Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN01A00 | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 2 usio n N umb er: | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

| | | | | |
|--|--|--|---|--|
| | | | <p>Crit Participants w erio ho are willing n De and able to co scri mply with all ptio scheduled visi n: ts, vaccination plan, laborator y tests, lifestyl e consideratio ns, and other s tudy procedur es</p> <p>Crit YES erio n m et?:</p> <p>Crit IN02A00 erio n ID : (F or P fizer use only):</p> | |
|--|--|--|---|--|

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

1.b Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

1.b Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participants who are willing and able to c omply with all sched uled visits, vaccinati on plan, laboratory t ests, lifestyle consid erations, and other st udy procedures | Initial Entry |

1.b Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN02A00 | Initial Entry |
|--|-----------------|------------------|-------------------------------|---------------|

I.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 3 usio n N umb er: Crit Healthy partic erio ipants who are n D determined by escr medical histor iptio y, physical exa n: mination, and clinical judgm ent of the inve stigator to be e ligible for incl usion in the st udy Crit YES erio n m et?: | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

| | | | | |
|--|--|--|---|--|
| | | | Crit erio n ID : (F or P fizer use only): | |
|--|--|--|---|--|

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

I.c Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

I.c Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Healthy participants who are determined by medical history, p hysical examination, and clinical judgmen t of the investigator t o be eligible for incl usion in the study | Initial Entry |

I.c Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN03A00 | Initial Entry |
|--|-----------------|------------------|-------------------------------|---------------|

1.d

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 4 usio n N umb er: Crit Capable of gi erio ving personal n De signed inform scri ed consent, w ptio hich includes n: compliance wi th the require ments and rest rictions listed in the ICD an d in this proto col Crit YES erio n m et?: | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

| | | | | |
|--|--|--|---|--|
| | | | Crit IN04A00 erio n ID : (F or P fizer use only): | |
|--|--|--|---|--|

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

1.d Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 4 | Initial Entry |

1.d Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN04A00 | Initial Entry |
|--|-----------------|------------------|-------------------------------|---------------|

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 1 usio n N um ber: Crit Other medical erio or psychiatric n D condition incl. escr recent (within ipti past year) or a on: ctive suicidal i deation/behavi or/lab abnorm ality that may increase the ri sk of study par ticipation Crit NO erio n m et?: | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|--|--|---|--|
| | | | Crit EX01A00 erio n ID : (F or P fize r us e on ly): | |
|--|--|--|---|--|

2.a Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Other medical or psy chiatric condition inc l. recent (within past year) or active suicid al ideation/behavior/ lab abnormality that may increase the risk of study participatio n | Initial Entry |

2.a Criterion met?

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX01A00 | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 2 usion Num ber: Crite Known infect rion ion with hum Desc an immunode ripti ficiency virus on: (HIV), hepati tis C virus (H CV), or hepat itis B virus (HBV) | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

| | | | | |
|--|--|--|--|--|
| | | | | |
| | | | | Crite NO rion met? : Crite EX02A00 rion ID: (For Pfize r use only) : |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.b Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

2.b Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX02A00 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|-----------------|--|--|--|--|
| of Buenos Aires | | | | |
|-----------------|--|--|--|--|

2.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 3 usio n N umb er: Crit History of sev erio ere adverse re n De action associat scri ed with a vacc ptio ine and/or sev n: ere allergic re action (eg, ana phylaxis) to a ny component of the study in tervention(s) Crit NO erio n m et?: | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|--|--|---|--|
| | | | Crit EX03A00 erio n ID : (F or P fizer use only): | |
|--|--|--|---|--|

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

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2.c Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

2.c Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: History of severe ad verse reaction associ ated with a vaccine a nd/or severe allergic reaction (eg, anaphyl axis) to any compon ent of the study inter vention(s) | Initial Entry |

2.c Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

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Visit: V1_DAY1_VAX1_L

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX03A00 | Initial Entry |
|--|-----------------|------------------|-------------------------------|---------------|

2.d

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusi 4 on Nu mber: Criteri Receipt of on Desc medication ription: s intended to prevent COVID-19 Criteri NO on met ?: Criteri EX04A00 on ID: (For Pfi zer use only): | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.d Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 4 | Initial Entry |

2.d Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Receipt of medicatio ns intended to preve nt COVID-19 | Initial Entry |

2.d Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX04A00 | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.e

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 8 usio n Nu mbe r: Crit Immunocomp erio romised indiv n De iduals with kn scri own or suspec ptio ted immunode n: ficiency, as de termined by h istory and/or l aboratory/phy sical examinatio Crit NO erio n me t?: Crit EX08A00 erio n ID : (Fo r Pfi zer use only): | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.e Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 8 | Initial Entry |

2.e Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX08A00 | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

(UTC-03:00) City
of Buenos Aires

2.f

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 10 usio n N umb er: Crit Bleeding diat erio hesis or condit n De ion associated scri with prolonge ptio d bleeding tha n: t would, in the opinion of the investigator, c ontraindicate i ntramuscular i njection Crit NO erio n m et?: | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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| | | | | |
|--|--|--|---|--|
| | | | Crit EX10A00 erio n ID : (Fo r Pfi zer use only): | |
|--|--|--|---|--|

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.f Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 10 | Initial Entry |

2.f Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bleeding diathesis or condition associated with prolonged bleed ing that would, in th e opinion of the inve stigator, contraindica te intramuscular inje ction | Initial Entry |

2.f Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX10A00 | Initial Entry |
|--|-----------------|------------------|-------------------------------|---------------|

2.g

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (For Pfizer use only): EX11A00 | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.g Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 11 | Initial Entry |

2.g Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Women who are pre gnant or breastfeedin g | Initial Entry |

2.g Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX11A00 | Initial Entry |

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Header Text: C4591001

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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.h

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: (For Pfizer use only): EX12A00 | Initial Entry |

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Header Text: C4591001

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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.h Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 12 | Initial Entry |

2.h Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Previous vaccination with any coronavirus vaccine | Initial Entry |

2.h Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX12A00 | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.i

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: NO Criterion ID: EX13A01 Dose (Formulation or Pfizer use only): | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.i Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 13 | Initial Entry |

2.i Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Subjects who receive immunosuppressive therapy, such as cyto toxic agents or syste mic corticosteroids | Initial Entry |

2.i Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX13A01 | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

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2.j

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 15 usio n N umb er: Crit Receipt of blo erio od/plasma pro n De ducts or immu scri noglobulin, fr ptio om 60 days be n: fore study inte rvention admi nistration or p lanned receipt throughout th e study Crit NO erio n m et?: Crit EX14A01 erio n ID : (Fo r Pfi zer use only): | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.j Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 15 | Initial Entry |

2.j Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

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Header Text: C4591001

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Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

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| | | | | |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX14A01 | Initial Entry |
|--|-----------------|------------------|-------------------------------|---------------|

Header Text: C4591001

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Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor
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Subject No: 12313184

Subject Initials: ---

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2.k

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>Exclusion Number: 16</p> <p>Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX15A01</p> <p>For Pfizer use only:</p> | Initial Entry |

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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: 12313184

Subject Initials: ---

Generated By: (b) (4)

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2.k Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 16 | Initial Entry |

2.k Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Aug-22-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

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Header Text: C4591001

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

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| | | | | |
|---|--|------------------|---------|--|
| 15:19:27 (UTC-03:00) City of Buenos Aires | | (b) (4), (b) (6) | EX15A01 | |
|---|--|------------------|---------|--|

2.1

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: Criterion ID: (Formerly only): EX16A01 | Initial Entry |

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Header Text: C4591001

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Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

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2.1 Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 17 | Initial Entry |

2.1 Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Previous participatio n in other studies in volving study interv ention containing lip id nanoparticles | Initial Entry |

2.1 Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.1 Criterion ID: (For Pfizer use only)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX16A01 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|-----------------|--|--|--|--|
| of Buenos Aires | | | | |
|-----------------|--|--|--|--|

2.m

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exc 22 lusi on Nu mbe r: Crit Investigator si erio te staff or Pfiz n D er employees escr directly invol ipti ved in the con on: duct of the stu dy, site staff o therwise super vised by the i nvestigator, a nd their respe ctive family m embers Crit NO erio n m et?: | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313184

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 20:20

| | | | | |
|--|--|--|---|--|
| | | | Crit EX21A01 erio n I D: (For Pfiz er u se o nly) : | |
|--|--|--|---|--|

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

2.m Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 22 | Initial Entry |

2.m Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|------------------|-------------------------------|---------------|
| Aug-22-2020 15:19:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX21A01 | Initial Entry |
|--|-----------------|------------------|-------------------------------|---------------|

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - 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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-22-2020 15:19:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/22/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-22-2020 15:19:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------------|---------------|
| Aug-22-2020 15:19:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-04-2021 10:42:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Term: Cholecystectomy Start Date: Jan/1/2016 Ongoing: NO End Date: Jan/1/2016 | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 10:42:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------------|---------------------------------------|---------------|
| Feb-04-2021 10:42:46 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Cholecystectomy | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|----------------------------------|--|------------------|--|--|
| (UTC-03:00) City of Buenos Aires | | (b) (4), (b) (6) | | |
|----------------------------------|--|------------------|--|--|

1.a Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Feb-04-2021 10:42:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/1/2016 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-04-2021 10:42:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Jan/1/2016 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/22/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 82.5 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 183.0 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|-----------------|--|--|--|--|
| of Buenos Aires | | | | |
|-----------------|--|--|--|--|

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|----------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 24.6 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Id 1 entifier:: Temperatu 36.3 re: Temperatu C re Unit: Temperatu ORAL re Locatio CAVIT n:: Y | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.3 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Aug-22-2020 15:20:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

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 20:20

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Aug-22-2020 15:20:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/22/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------|---------------|
| Aug-22-2020 15:20:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 62043 | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

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 20:20

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-22-2020 15:20:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Aug-22-2020 15:20:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------|---|
| Aug-28-2020 23:26:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Aug-24-2020 02:52:40 (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 |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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:** 12313184**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:20

| | | | | |
|--|-----------------|---------------------------|---|---|
| | | | | appropriate. |
| Aug-22-2020 15:20:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-22-2020 15:20:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection : Aug/22/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-28-2020 23:26:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BHY6N : B | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-28-2020 23:26:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BHY6NB | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-28-2020 23:26:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BHY6N : C | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-28-2020 23:26:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BHY6NC | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-28-2020 23:26:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BHY6N : D | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-28-2020 23:26:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BHY6ND | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-29-2020 15:42:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BJ49YR | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-29-2020 15:42:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BJ49YR | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-29-2020 15:42:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BJ49YS | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-29-2020 15:42:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BJ49YS | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-29-2020 15:42:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BJ49YT | Initial Entry |

5.f Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-29-2020 15:42:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BJ49YT | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-22-2020 15:20:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-22-2020 15:20:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------|---|
| Aug-28-2020 21:27:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Aug-24-2020 02:52:40 (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 |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|---------------------------|---|---|
| | | | | appropriate. |
| Aug-22-2020 15:20:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-22-2020 15:20:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection : Aug/22/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-28-2020 21:27:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP2CGJ | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-28-2020 21:27:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP2CGJ | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

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 20:20

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/22/2020 14:35 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

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 20:20

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPEC IFIED OBSERVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

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 20:20

investigational product administration?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Aug-22-2020 15:20:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-22-2020 15:20:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-10-2020 19:03:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/10/2020 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-10-2020 19:04:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/10/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-10-2020 19:04:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: Temperature 36.5 : Temperature C Unit: Temperature ORAL C Location: AVITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-10-2020 19:04:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313184

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 20:20

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-10-2020 19:04:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 36.5 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-10-2020 19:04:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> C | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-10-2020 19:04:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> ORAL CAVITY | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-10-2020 19:04:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-10-2020 19:04:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------|---|
| Sep-11-2020 10:31:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-11-2020 03:13:02 (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 |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|--------------------------------|---|---|
| | | | | appropriate. |
| Sep-10-2020 19:04:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-10-2020 19:04:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: YES Date of Collection: Sep/10/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---|--|---------------|
| Sep-11-2020 10:31:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), [Redacted] (b) (6) [Redacted] | Data Entry: Sample ID: BP242K | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---|------------------------------|---------------|
| Sep-11-2020 10:31:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), [Redacted] (b) (6) [Redacted] | Data Entry: BP242K | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

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 20:20

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/10/2020 17:20 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

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 20:20

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPEC IFIED OBSERVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

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 20:20

investigational product administration?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-10-2020 19:04:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|--|
| Oct-20-2020 02:51:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-19-2020 09:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | EOT form completed |
| Oct-19-2020 07:41:55 (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-15-2020 08:41:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/14/2020 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-15-2020 08:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-15-2020 08:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Oct-15-2020 10:19:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-15-2020 08:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|---------------------|---|---------------|
| | | | | appropriate. |
| Oct-15-2020 08:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/14/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-15-2020 10:19:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP1NM6 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 10:19:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP1NM6 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-15-2020 11:25:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRXS61 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 11:25:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRXS61 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-15-2020 12:58:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRXS6X | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 12:58:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRXS6X | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Mar-16-2021 17:04:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/16/2021 | Initial Entry |

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

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 20:20

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-16-2021 17:04:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Mar-16-2021 17:04:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------|---|
| Mar-17-2021 10:24:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-17-2021 05:11:03 (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 |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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:** 12313184**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:20

| | | | | |
|--|-----------------|---------------------------|---|---|
| | | | | appropriate. |
| Mar-16-2021 17:04:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-16-2021 17:04:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/16/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Mar-17-2021 10:24:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BRMRN D: Z | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Mar-17-2021 10:24:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRMRNZ | Initial Entry |

5.b

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Mar-17-2021 11:46:05 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BRZ2X : 1 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Mar-17-2021 11:46:05 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRZ2X1 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Mar-17-2021 13:17:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BRZ2X : H | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Mar-17-2021 13:17:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRZ2XH | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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: 12313184 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 20:20

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-----------------------------------|---------------|
| Oct-19-2020 09:56:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Oct/14/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-19-2020 09:56:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---------------------------------|---------------|
| Oct-19-2020 09:56:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Mar-11-2021 16:26:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/11/2021 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION -
eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Mar-11-2021 16:26:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT co nfirmed to have rece ived only placebo at Vaccination 1/2 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313184

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 20:20

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|-------------------------------------|---------------|
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|-------------------------|---------------|
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------|---|
| Mar-02-2021 16:07:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Feb-27-2021 10:47:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | According to the instructions given by ICON and by CCG right hand carpal tunnel and left hand carpal tunnel, two different events are considered. |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|---------------------|---|--|
| | | | | Thank you. |
| Feb-24-2021 10:19:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | Clinical - Event term is RIGHT carpal tunnel syndrome; however, SAE report states subject has scheduled surgery for LEFT side in March, after surg on RIGHT in Feb. Please review for Bilateral vs Right carpal tunnel & update in AE/SAE report as required |
| Feb-20-2021 16:22:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : right carpal tunnel syndrome | New Information |
| Feb-12-2021 14:13:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-08-2021 11:42:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-07-2021 10:42:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Elective surgery was scheduled in the right hand and a second time left hand. Right hand surgery was |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|------------------------|--|---|
| Aires | | | | performed on FEB 02, 2021. The patient has got history of cholecystectomy due to gallstones. |
| Feb-05-2021 16:46:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Re issued: Opened | CLINQUERY: for the event "Bilateral carpal tunnel syndrome" please clarify if surgery was planned. If so provide details in the response to this query. Please also clarify if the subject has a history of carpal tunnel syndrome. |
| Feb-05-2021 13:58:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |
| Feb-05-2021 13:58:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Feb-05-2021 13:58:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Bilateral carpal tunnel syndrome | Transcription Error |
| Feb-05-2021 10:43:15 (UTC-03:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON:AER#2021112498, the term in AE CRF is |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|------------------|---|--|
| City of Buenos Aires | | | | 'Sindrome del tunel carpiano bilateral' but term in SDB is Bilateral carpal tunnel syndrome'. Please confirm correct term. If safety update is required, please submit a follow-up form. |
| Feb-03-2021 19:03:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: for the event "Sindrome del tunel carpiano bilateral" please clarify if surgery was planned. If so provide details in the response to this query. Please also clarify if the subject has a history of carpal tunnel syndrome. |
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Sindrome del tunel carpiano bilateral | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/15/2020 20:00 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------------------|---|--------------------|
| Feb-20-2021 16:23:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO End Date Time: Feb/19/2021 12:00 | New Information |
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------------------|-------------------------|---------------|
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------|------------------|------------|
| Feb-05-2021 | ACV0PFEINFP6000 | auto query | Query 1: Deleted | Close Auto |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|---|-----------------|---------------------------|---|---|
| 10:37:48 (UTC-03:00) City of Buenos Aires | | (autoquery) | | Query |
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Sindrome del tunel carpiano bilateral: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event as sociated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313184**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:20

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

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event | Initial Entry |

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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|--|--|---------------------------|--|
| | | | is due to: | |
| | | | OTHER | |
| | | | <i>If Other, specify:</i> | |
| | | | unknown | |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|-----------------|
| Feb-13-2021 10:33:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | New Information |
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Feb-02-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | |
|--|------------------|-----|
| 17:38:56 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | YES |
|--|------------------|-----|

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|----------------------------|---|
| Feb-24-2021 10:09:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | 20Feb21 SAE update has resolved status / end date added |
| Feb-24-2021 01:59:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON:AER#2021112498,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database.Please confirm correct outcome.If safety update is required, please submit a ffup form |
| Feb-20-2021 16:23:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-20-2021 16:23:49 (UTC-03:00) City of | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : REC | New Information |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|---|-----------------|------------------------|---|---|
| Buenos Aires | | | OVERSOLVED | |
| Feb-20-2021 16:23:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE right carpal tunnel syndrome: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present. |
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : RECOVERING/RESOLVING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------|--------------------------|
| Feb-08-2021 14:36:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-08-2021 07:59:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|--|-----------------|---------------------------|--------------------------|---|
| Feb-07-2021 10:36:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |
| Feb-07-2021 10:36:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Feb-07-2021 10:36:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Transcription Error |
| Feb-04-2021 09:35:36 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | DM: Did the event cause the Subject to be Discontinued from the Study" is marked 'YES', but 'Disposition - Follow-Up' is not completed. Kindly verify and update. |
| Feb-03-2021 19:17:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: please clarify if event, "Sindrome del tunel carpiano bilateral," was the reason the subject was discontinued |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (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

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

| | | | | |
|---|-----------------|------------------|---------------------------|---|
| | | | | from the study. If so please complete the disposition follow-up to reflect Adverse Event. |
| Feb-02-2021 17:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Feb-05-2021 10:37:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2021112498 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313184

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

[Back to Form](#)

1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-----------------------------------|---------------|
| Mar-11-2021 16:26:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Mar/11/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--|---------------|
| Mar-11-2021 16:26:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL V ACCINATION | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:20

[Back to Form](#)

1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Oct-19-2020 09:56:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Aug-22-2020 15:20:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOM IZED | Initial Entry |
| Aug-22-2020 15:19:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-19-2020 09:56:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/14/2020 | Initial Entry |
| Aug-22-2020 15:20:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/22/2020 | Initial Entry |
| Aug-22-2020 15:19:35 | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/22/2020 | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:20

(UTC-03:00) City
of Buenos Aires

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313184

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:20

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1. Casebook Signature

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Oct-22-2020 15:34:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enabl e | Initial Entry |

090177e196ae2e79\Final\Final On: 01-Apr-2021 03:14 (GMT)