

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[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 |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/24/2020 |
|----|--------------|--|

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [12313689] |
| 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: | |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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/24/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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 |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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: ---

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

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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.b | Exclusion Number: | 2 |
| | Criterion Description: | Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX02A00 |
| 2.c | Exclusion Number: | 3 |
| | Criterion Description: | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX03A00 |
| 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 |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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.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: 12313689

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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/24/2020 |
| 2. | Phase of Disposition: | SCREENING |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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

Medical History Details

| | | |
|----|--|--------------------------------|
| 1. | Line/MH Number: | Not Applicable _____ [] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | Not Applicable _____ [] |
| | Start Date: | Not Applicable _____ // |
| | Ongoing: | Not Applicable _____ |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Aug/24/2020 |
| 2. | Weight: | [78.8] |
| 3. | Unit: | kg |
| 4. | Height: | [180.0] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [24.3] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [36.5] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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/24/2020 |
| 2. | Randomization Number: | [64660] |
| 3. | Randomization Group: | [] |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 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/24/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP2DVW] |
| 5.b | Sample ID | [BP2DVX] |
| 5.c | Sample ID | [BP2DVY] |
| 5.d | Sample ID | [BLDZ8M] |
| 5.e | Sample ID | [BLDZ8N] |
| 5.f | Sample ID | [BLDZ8P] |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/24/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP24LL] |
|-----|-----------|----------|

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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/24/2020 18:15 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | RIGHT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12313689

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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/13/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/13/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [36.7] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/13/2020 |
| 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 | [BP2BW3] |
|-----|-----------|----------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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/13/2020 13:40 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | RIGHT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689 **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:** 12313689**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

[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 | [BP1NL0] |
| 5.b | Sample ID | [BRXS4V] |
| 5.c | Sample ID | [BRXS8R] |

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

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

COVID-19 Illness Visit

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 28-Mar-2021 02:35

Site No: 1231

Subject No: 12313689

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12313689**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 | [] |
|----|-----------|-----|

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 28-Mar-2021 02:23

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION

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

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: ILLNESS DETAILS

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

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

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

COVID-19 Illness Visit

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12313689**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 | [] |
|----|-----------|-----|

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: 12313689 **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: 12313689 **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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[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: | [] |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

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

COVID-19 Repeat Swab

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313689**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Unplanned 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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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? | |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1231

Subject No: 12313689

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Feb/9/2021 |
| 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: 12313689 **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 per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 |
|----|---|---|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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 | Feb/20/2021 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Feb/20/2021 |
|----|--------------|--|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

| | | |
|----|--|--------------------|
| 1. | Date of Completion/Discontinuation/Death : | Feb/20/2021 |
| 2. | Phase of Disposition: | REPEAT SCREENING 1 |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Feb/20/2021 |
| 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 | [BR21K7] |
| 5.b | Sample ID | [BLBXPY] |
| 5.c | Sample ID | [BLBXPY] |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Feb/20/2021 |
| 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 | [BRM9HP] |
|-----|-----------|----------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313689

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 | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Feb/20/2021 14:45 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | RIGHT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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/11/2021 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V102_VAX4

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Mar/11/2021 |
| 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 | [BR1WNC] |
|-----|-----------|----------|

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313689

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 | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Mar/11/2021 15:40 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | RIGHT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: CONTACT OUTCOME

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: | [] |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: CONTACT OUTCOME

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: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: CONTACT OUTCOME

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: | [] |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

Disposition - Treatment

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|---------------|-------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Cholecystitis | Dec/25/2020 23:00 | NO End Date Time: Jan/28/2021 18:00 | Repeating Pages |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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

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[Form Audit Trail](#)

Adverse Event Report

| | | |
|----|--|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Cholecystitis] |
| 4. | Start Date Time: | Dec/25/2020 23:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Jan/28/2021 18:00 |
| 6. | Toxicity Grade: | 2 |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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?</p> <p>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?</p> <p>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> |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | |
|-----|--|--------------------|
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2021191663] |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1231

Subject No: 12313689

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

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Medication Error

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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Concomitant Medications

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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Concomitant Medications

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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

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Radiation Treatment

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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 : | Feb/9/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: DEATH DETAILS CODED

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

Death Details

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

Cause of Death

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[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 Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

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

[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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|---------------|-------------------|--|------|--------|
| Maria Beretta | Approved | Mar-17-2021 15:18:26 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

Affidavit:

By my dated signature below, I, MariaBeretta, 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.

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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 | Aug-24-2020 19:57:26 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|------------------|----------------|
| Form | Feb-20-2021 19:40:25 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[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 |
|---------------|-------------------|--|------|--------|
| Maria Beretta | Approved | Mar-17-2021 15:18:26 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

Affidavit:

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

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

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

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Mar-11-2021 17:10:57 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------|----------|--|------|--------|
| (b) (6) | Approved | Mar-09-2021 11:45:00 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|--|------|--------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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-23-2021 23:27:08 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------|----------|--|------|--------|
| (b) (6) | Approved | Feb-22-2021 20:10:50 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|--|------|--------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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-10-2021 17:46:16 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
| Affidavit: N/A | | | | |
| (b) (6) | Approved | Oct-21-2020 22:24:28 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
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

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: COHORT SELECTION - eCRF Audit Trail History

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-24-2020 19:56:01 (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-24-2020 19:56:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT - 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. Consent Was:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|--|---------------|
| Aug-24-2020 19:56:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consen t Obtained Aug/24/2020 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12313689

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-24-2020 17:16:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12313689 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Aug-24-2020 17:16:39 (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-24-2020 19:56:23 (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-24-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | |
|---|---------------------|--|
| 19:56:23 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | HISPANIC OR LATI NO(A) OR OF SPANI SH ORIGIN |
|---|---------------------|--|

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|-----------------------------|---------------|
| Aug-24-2020 19:56:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|-----------------------------------|---------------|
| Aug-24-2020 19:56:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/24/2020 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

I.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>Incl 1 usio n N umb er:</p> <p>Crit Male or female erio participants bet n D ween the ages o escr f 18 and 55 year iptio s, inclusive, 65 n: and 85 years, in clusive, or 18 a nd 85 years, inc lusive, at rando mization (depen dent upon study stage)</p> <p>Crit YES erio n m et?:</p> | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|--|--|--|--|
| | | | Crit IN01A00 erion ID : (F or P fizer use only): | |
|--|--|--|--|--|

1.a Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (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 |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

1.a Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 2 usio n Nu mbe r: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|--|--|--|--|
| | | | <p>Crit Participants wh erio o are willing an n De d able to compl scri y with all sched ptio uled visits, vac n: cination plan, l aboratory tests, lifestyle consid erations, and ot her study proce dures</p> <p>Crit YES erio n me t?:</p> <p>Crit IN02A00 erio n ID : (Fo r Pfi zer use only):</p> | |
|--|--|--|--|--|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

1.b Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, life style considerations, and other study procedures | Initial Entry |

1.b Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-24-2020 19:56:59 (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)

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN02A00 | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 3 usio n N umb er: Crit Healthy partici erio pants who are d n De etermined by m scri edical history, p ptio hysical examin n: ation, and clinic al judgment of t he investigator to be eligible fo r inclusion in th e study Crit YES erio n m et?: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|--|--|---|--|
| | | | Crit IN03A00 erio n ID : (Fo r Pfi zer use only): | |
|--|--|--|---|--|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

1.c Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

1.c Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Healthy participants w ho are determined by medical history, physi cal examination, and c linical judgment of the investigator to be eligi ble for inclusion in the study | Initial Entry |

1.c Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 4 usio n Nu mbe r: Crit Capable of givi erio ng personal sig n De ned informed c scrip onsent, which i tion: ncludes compli ance with the re quirements and restrictions liste d in the ICD an d in this protoc ol Crit YES erio n me t?: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|--|--|---|--|
| | | | Crit IN04A00 erio n ID : (Fo r Pfi zer use only): | |
|--|--|--|---|--|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

1.d Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (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-24-2020 19:56:59 (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)

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 1 usio n N umb er: Crit Other medical o erio r psychiatric co n De ndition incl. rec scri ent (within past ptio year) or active s n: uicidal ideation/ behavior/lab ab normality that may increase th e risk of study p articipation Crit NO erio n m et?: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|--|--|---|--|
| | | | Crit EX01A00 erio n ID : (Fo r Pfi zer use only): | |
|--|--|--|---|--|

2.a Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Other medical or psyc hiatric condition incl. recent (within past yea r) or active suicidal id eation/behavior/lab ab normality that may inc rease the risk of study participation | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.a Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclu 2 sion Num ber: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|--|--|--|--|
| | | | <p>Crite Known infecti tion on with human Descr immunodefici iptio ency virus (HI n: V), hepatitis C virus (HCV), or hepatitis B virus (HBV)</p> <p>Crite NO tion met?:</p> <p>Crite EX02A00 tion I D: (F or Pfi zer u se onl y):</p> | |
|--|--|--|--|--|

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.b Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Known infection with human immunodeficie ncy virus (HIV), hepat itis C virus (HCV), or hepatitis B virus (HB V) | Initial Entry |

2.b Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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 |
|------|----------|------|-------|--------|
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090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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|--|-----------------|------------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX02A00 | Initial Entry |
|--|-----------------|------------------------|-------------------------------|---------------|

2.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|---|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 3 usio n Nu mbe r: Crit History of severe erio re adverse reaction n De ion associated scrip with a vaccine tion: and/or severe allergic reaction (eg, anaphylaxis)) to any component of the study intervention(s)) Crit NO erio n me t?: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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|--|--|--|---|--|
| | | | Crit EX03A00 erio n ID : (Fo r Pfi zer use only): | |
|--|--|--|---|--|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.c Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) | Initial Entry |

2.c Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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|--|-----------------|------------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19 Criterion met?: NO Criterion ID: (For Pfizer use only): EX04A00 | Initial Entry |

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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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.d Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Receipt of medication s intended to prevent COVID-19 | Initial Entry |

2.d Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City | 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 Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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| of Buenos Aires | (b) (4), (b) (6) |
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2.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 8 usio n Nu mbe r: Crit Immunocompr erio omised individ n De uals with know scrip n or suspected i tion: mmunodeficien cy, as determin ed by history a nd/or laborator y/physical exa mination Crit NO erio n me t?: | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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

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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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.e Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Immunocompromised individuals with know n or suspected immun odeficiency, as determ ined by history and/or laboratory/physical ex amination | Initial Entry |

2.e Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

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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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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|--|-----------------|------------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX08A00 | Initial Entry |
|--|-----------------|------------------------|-------------------------------|---------------|

2.f

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|---|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 10 usio n Nu mbe r: Crit Bleeding diathe erio sis or condition n De associated with scrip prolonged blee tion: ding that would , in the opinion of the investiga tor, contraindic ate intramuscul ar injection Crit NO erio n me t?: | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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

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|--|--|--|--|--|
| | | | Crit EX10A00 erio n ID : (Fo r Pfi zer u se on ly): | |
|--|--|--|--|--|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.f Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection | Initial Entry |

2.f Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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|--|-----------------|------------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 11 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

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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: 12313689

Subject Initials: ---

Generated By:

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(b) (4)

2.g Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Women who are pregn ant or breastfeeding | Initial Entry |

2.g Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX11A00 | 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: 12313689

Subject Initials: ---

Generated By:

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(b) (4)

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| of Buenos Aires | (b) (4), (b) (6) |
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2.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-24-2020 19:56:59 (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

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.h Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (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-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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|-----------------|------------------|--|--|
| of Buenos Aires | (b) (4), (b) (6) | | |
|-----------------|------------------|--|--|

2.i

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>Exclusion Number:</p> <p>Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX13A01</p> <p>D: (F or Pfizer use only):</p> | Initial Entry |

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Header Text: C4591001

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Site No: 1231

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Subject No: 12313689

Subject Initials: ---

Generated By:

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(b) (4)

2.i Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Subjects who receive i mmunosuppressive th erapy, such as cytotoxi c agents or systemic c orticosteroids | Initial Entry |

2.i Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

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Site No: 1231

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Subject No: 12313689

Subject Initials: ---

Generated By:

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(b) (4)

| | | | | |
|--|-----------------|------------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX13A01 | Initial Entry |
|--|-----------------|------------------------|-------------------------------|---------------|

2.j

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|--|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 15 usio n Nu mbe r: Crit Receipt of bloo erio d/plasma produ n De cts or immunog scrip lobulin, from 6 tion: 0 days before st udy interventio n administratio n or planned re ceipt throughou t the study Crit NO erio n me t?: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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 EX14A01 erio n ID : (Fo r Pfi zer u se on ly): | |
|--|--|--|--|--|

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.j Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (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-24-2020 19:56:59 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|------------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX14A01 | Initial Entry |
|--|-----------------|------------------------|-------------------------------|---------------|

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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2.k

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-24-2020 19:56:59 (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 (For Pfizer use only)</p> | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.k Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participation in other studies involving stud y intervention within 28 days prior to study entry and/or during st udy participation | Initial Entry |

2.k Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX15A01 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

2.1

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclu 17 sion Numb er: Cr iter Previous parti ion D cipation in ot escrip her studies in tion: volving study intervention c ontaining lipi d nanoparticl es Cr iter NO ion m et?: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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

| | | | | |
|--|--|--|---|--|
| | | | Criterion I D: (Former Pfizer 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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.1 Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Previous participation in other studies involv ing study intervention containing lipid nano particles | Initial Entry |

2.1 Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX16A01 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

2.m

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 22 usio n N umb er: Crit Investigator sit erio e staff or Pfizer n De employees dire scri ctly involved in ptio the conduct of t n: he study, site st aff otherwise s upervised by th e investigator, a nd their respect ive family mem bers Crit NO erio n m et?: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313689

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

2.m Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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-24-2020 19:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Investigator site staff or Pfizer employees d irectly involved in the conduct of the study, s ite staff otherwise sup ervised by the investi gator, and their respec tive family members | Initial Entry |

2.m Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-24-2020 19:56:59 (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)

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-24-2020 19:56:59 (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 Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|-----------------------------------|---------------|
| Aug-24-2020 19:57:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/24/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-24-2020 19:57:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|---------------------------------|---------------|
| Aug-24-2020 19:57:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/24/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 78.8 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Aug-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: kg | Initial Entry |

4. Height:

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|------------------|-----------------------------|---------------|
| Aug-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 180.0 | Initial Entry |
|---|-----------------|------------------|-----------------------------|---------------|

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Aug-24-2020 19:58:01 (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-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 24.3 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Aug-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: 1 Temperature: 36.5 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

Temperature Unit:
Temperature Location: ORAL
CAVITY

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Aug-24-2020 19:58:01 (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-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.5 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Aug-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-24-2020 19:58:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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-24-2020 19:58:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/24/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-24-2020 19:58:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 64660 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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-24-2020 19:58:32 (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-24-2020 19:58:32 (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-25-2020 10:48:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Aug-25-2020 03:42:32 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|------------------------|---|--|
| | | | | are entered. Please review and correct as appropriate. |
| Aug-24-2020 19:58:32 (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-24-2020 19:58:32 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/24/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Aug-25-2020 10:48:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | Data Entry: Sample I BP2DV D: W | Initial Entry |

5.a Sample ID

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|---------------------------|------------------------------|---------------|
| Aug-25-2020 10:48:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | Data Entry: BP2DVW | Initial Entry |
|---|-----------------|---------------------------|------------------------------|---------------|

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Aug-25-2020 10:48:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | Data Entry: Sample I BP2DV D: X | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|------------------------------|---------------|
| Aug-25-2020 10:48:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | Data Entry: BP2DVX | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Aug-25-2020 10:49:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | Data Entry: Sample I BP2DV D: Y | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|------------------------------|---------------|
| Aug-25-2020 10:49:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | Data Entry: BP2DVY | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-25-2020 14:44:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BLDZ8 D: M | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-25-2020 14:44:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLDZ8M | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-25-2020 14:44:53 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BLDZ8 D: N | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-25-2020 14:44:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLDZ8N | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-25-2020 14:45:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BLDZ8 D: P | Initial Entry |

5.f Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-25-2020 14:45:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLDZ8P | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-24-2020 19:58:40 (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-24-2020 19:58:40 (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-25-2020 12:50:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Aug-25-2020 03:42:32 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|------------------------|---|--|
| | | | | are entered. Please review and correct as appropriate. |
| Aug-24-2020 19:58:40 (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-24-2020 19:58:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/24/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Aug-25-2020 12:50:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | Data Entry: Sample ID BP24L : L | Initial Entry |

5.a Sample ID

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|------------------------------|-------------------------------------|---------------|
| Aug-25-2020 12:50:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | <u>Data Entry:</u> BP24LL | Initial Entry |
|--|-----------------|------------------------------|-------------------------------------|---------------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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-24-2020 19:59:13 (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-24-2020 19:59:13 (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-24-2020 19:59:13 (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-24-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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

19:59:13
(UTC-03:00) City
of Buenos Aires

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

Aug/24/2020 18:15

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-24-2020 19:59:13 (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-24-2020 19:59:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-24-2020 19:59:13 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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

| | | | | |
|--|-----------------|-------------------------|---|---------------|
| Aug-24-2020 19:59:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD | Initial Entry |
|--|-----------------|-------------------------|---|---------------|

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-24-2020 19:59:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|---|---------------|
| Aug-24-2020 19:59:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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-13-2020 15:24:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/13/2020 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313689

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

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-13-2020 15:24:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/13/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-13-2020 15:24:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: : Temperature: Temperature Unit: Temperature Location: Temperature Unit: ORAL CAVI TY | Initial Entry |

2.a Record Identifier:

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-13-2020 15:24:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |
|--|-----------------|---------------------|-------------------------|---------------|

2.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-13-2020 15:24:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.7 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-13-2020 15:24:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-13-2020 15:24:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313689

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

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090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-13-2020 15:24:21 (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-13-2020 15:24:21 (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-14-2020 08:34:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-14-2020 02:38:59 (UTC-03:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|------------------------|---|--|
| City of Buenos Aires | | | | no barcodes are entered. Please review and correct as appropriate. |
| Sep-13-2020 15:24:21 (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-13-2020 15:24:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/13/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-14-2020 08:34:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BP2BW D: 3 | Initial Entry |

5.a Sample ID

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|------------------------------|---------------|
| Sep-14-2020 08:34:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: BP2BW3 | Initial Entry |

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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-13-2020 15:24:37 (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-13-2020 15:24:37 (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-13-2020 15:24:37 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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

| | | | | |
|--|-----------------|---------------------|---|---------------|
| Sep-13-2020 15:24:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/13/2020 13:40 | Initial Entry |
|--|-----------------|---------------------|---|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-13-2020 15:24:37 (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-13-2020 15:24:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-13-2020 15:24:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-13-2020 15:24:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-13-2020 15:24:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 08:59:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/14/2020 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689 **Subject Initials:** ---

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

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-15-2020 08:59:39 (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 08:59:39 (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 09:41:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-15-2020 08:59:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689 **Subject Initials:** ---

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

(b) (4)

| | | | | |
|---|-----------------|---------------------|---|--|
| | | | | are entered. Please review and correct as appropriate. |
| Oct-15-2020 08:59:39 (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 09:41:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral (b) (4) | Data Entry: Sample ID BP1NL : 0 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Oct-15-2020 09:41:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral (b) (4) | Data Entry: BP1NL0 | Initial Entry |

5.b

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689 Subject Initials: ---

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

(b) (4)

| | | | | |
|--|-----------------|---------------------|---|---------------|
| Oct-15-2020 09:51:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BRXS4 : V | Initial Entry |
|--|-----------------|---------------------|---|---------------|

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 09:51:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRXS4V | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-15-2020 10:49:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BRXS8 : R | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 10:49:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRXS8R | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Oct-16-2020 16:47:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/14/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|-----------------------------------|---------------|
| Oct-16-2020 16:47:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------------|---------------|
| Oct-16-2020 16:47:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Feb-10-2021 17:46:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/9/2021 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled 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: 12313689 **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 |
|--|-----------------|---------------------------|--|--|
| Feb-10-2021 17:46:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-10-2021 17:46:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Feb-10-2021 17:46:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willin g to return for Vacc ination 3 Participant is: eligible per othe r protocol allow ance(s) and conf | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled 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: 12313689 **Subject Initials:** ---

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

(b) (4)

| | | | | |
|--|--|--|--|--|
| | | | irmed to have re ceived only plac ebo at Vaccinati on 1/2 | |
|--|--|--|--|--|

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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 |
|--|-----------------|------------------------|-----------------------------------|---------------|
| Feb-20-2021 19:40:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/20/2021 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Consent Was:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|--|---------------|
| Feb-20-2021 19:40:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consen t Obtained Feb/20/2021 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1231

Subject No: 12313689

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER 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. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|-----------------------------------|---------------|
| Feb-20-2021 19:40:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/20/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-20-2021 19:40:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|---------------------------------|---------------|
| Feb-20-2021 19:40:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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 |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-20-2021 19:41:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-20-2021 19:41:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------|--|
| Feb-22-2021 10:41:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-22-2021 08:29:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|------------------------|---|--|
| | | | | are entered. Please review and correct as appropriate. |
| Feb-20-2021 19:41:07 (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. |
| Feb-20-2021 19:41:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/20/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-22-2021 10:41:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: Sample I BR21K D: 7 | Initial Entry |

5.a Sample ID

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|-------------------------|------------------------------|---------------|
| Feb-22-2021 10:41:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: BR21K7 | Initial Entry |
|--|-----------------|-------------------------|------------------------------|---------------|

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Feb-22-2021 13:21:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BLBXP D: Y | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Feb-22-2021 13:21:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLBXPY | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-22-2021 15:23:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: Sample I BLBXP D: H | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313689

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

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|------------------------------|---------------|
| Feb-22-2021 15:23:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: BLBXPB | Initial Entry |

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-20-2021 19:41:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-20-2021 19:41:21 (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 |
|--|-----------------|---------------------------|-----------------|--|
| Feb-22-2021 13:36:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-22-2021 08:29:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313689**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

| | | | | |
|---|-----------------|---------------------------|---|--|
| | | | | are entered. Please review and correct as appropriate. |
| Feb-20-2021 19:41:21 (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. |
| Feb-20-2021 19:41:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/20/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-22-2021 13:36:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BRM9H D: P | Initial Entry |

5.a Sample ID

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

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|--------------------------------|-------------------------------------|---------------|
| Feb-22-2021 13:36:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | <u>Data Entry:</u> BRM9HP | Initial Entry |
|--|-----------------|--------------------------------|-------------------------------------|---------------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313689

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 |
|--|-----------------|------------------------|--------------------------|---------------|
| Feb-20-2021 19:41:46 (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 |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Feb-20-2021 19:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Feb-20-2021 19:41:46 (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 |
|-------------|-----------------|------------------|--------------------|---------------|
| Feb-20-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313689

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

19:41:46
(UTC-03:00) City
of Buenos Aires

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

Feb/20/2021 14:45

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-20-2021 19:41:46 (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 |
|--|-----------------|------------------------|-----------------------------|---------------|
| Feb-20-2021 19:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-20-2021 19:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-20-2021 19:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |
|--|-----------------|-------------------------|----------------------------|---------------|

9. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-20-2021 19:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-20-2021 19:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|---------------------------|---------------|
| Feb-20-2021 19:41:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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-11-2021 17:10:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/11/2021 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-11-2021 17:11:06 (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-11-2021 17:11:06 (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 |
|--|-----------------|---------------------------|-----------------|--|
| Mar-12-2021 09:43:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-12-2021 08:57:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|------------------------|---|--|
| | | | | are entered. Please review and correct as appropriate. |
| Mar-11-2021 17:11:06 (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-11-2021 17:11:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/11/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Mar-12-2021 09:43:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BR1WN D: C | Initial Entry |

5.a Sample ID

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|---------------------|------------------------------|---------------|
| Mar-12-2021 09:43:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR1WNC | Initial Entry |
|--|-----------------|---------------------|------------------------------|---------------|

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313689

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 |
|---|-----------------|------------------|--------------------------|---------------|
| Mar-11-2021 17:11:30 (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 |
|---|-----------------|----------------------|--------------------------------|---------------|
| Mar-11-2021 17:11:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|---------------------------------|---------------|
| Mar-11-2021 17:11:30 (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 |
|-------------|-----------------|------------------|--------------------|---------------|
| Mar-11-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313689

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

17:11:30
(UTC-03:00) City
of Buenos Aires

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

Mar/11/2021 15:40

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Mar-11-2021 17:11:30 (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 |
|--|-----------------|---------------------|-----------------------------|---------------|
| Mar-11-2021 17:11:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-11-2021 17:11:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-11-2021 17:11:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |
|--|-----------------|-------------------------|----------------------------|---------------|

9. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Mar-11-2021 17:11:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Mar-11-2021 17:11:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Mar-11-2021 17:11:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313689

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-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|-------------------------------------|---------------|
| Feb-20-2021 16:29:04 (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-20-2021 16:29:04 (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 16:14:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | GB ultrasound data submitted |
| Mar-02-2021 16:14:31 (UTC-03:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|------------------|----------------------------------|--|
| City of Buenos Aires | | | | |
| Mar-02-2021 10:54:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | On 27FEB2021 FU was sent with this updated information. |
| Mar-02-2021 07:01:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON: AER#2021191663, the term was reported as 'cholelithiasis' in Safety database while updated to 'Cholecystitis' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form. |
| Feb-27-2021 21:41:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Cholecystitis | New Information |
| Feb-24-2021 11:57:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | It's clarify that ther is no available imaging study that documenting the evidence for |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|---------------------|--------------------------------------|---|
| | | | | Cholelithiasis yet. Study Reports and Summary discharge were requested, subject will provide them. |
| Feb-23-2021 14:12:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical Please submit a SAE safety update documenting the evidence for Cholelithiasis, such as an imaging study. |
| Feb-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Cholelithiasis | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/25/2020 23:00 | Initial Entry |

5. Is the adverse event still ongoing?

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

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|---|-----------------|------------------|---|---------------|
| Feb-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Jan/28/2021 18:00 | Initial Entry |
|---|-----------------|------------------|---|---------------|

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Feb-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------|-----------------------------------|
| Feb-22-2021 00:51:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Deleted | Query can be addressed internally |
| Feb-20-2021 16:29:04 | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Cholelithiasis: |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-03:00) City of Buenos Aires

Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

Feb-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires

ACV0PFEINFP6000

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

Data Entry:

YES

Is this serious event associated with congenital anomaly or birth defect?

NO

Did this serious event result in death?

NO

Did this serious event require or prolong hospitalization?

YES

Did this serious event result in persistent or significant disability/incapacity?

Initial Entry

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|--|--|---|--|
| | | | NO | |
| | | | Is this serious event life threatening? | |
| | | | NO | |
| | | | Other medically important serious event | |
| | | | NO | |

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

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-20-2021 16:29:04 (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-20-2021 16:29:04 (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 is due to: | 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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-20-2021 16:29:04 (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-20-2021 16:29:04 (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-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-20-2021 16:29:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Feb-23-2021 23:27:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2021191663 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (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: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Feb-10-2021 17:46:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/9/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Feb-10-2021 17:46:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Oct-16-2020 16:47:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Aug-24-2020 19:58:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-24-2020 19:57:08 (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-16-2020 16:47:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/14/2020 | Initial Entry |
| Aug-24-2020 19:58:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/24/2020 | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313689

Subject Initials: ---

Generated By:

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

(b) (4)

| | | | | |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Aug-24-2020 19:57:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/24/2020 | Initial Entry |
|--|-----------------|-------------------------|-----------------------------------|---------------|

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313689

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-21-2020 22:24:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enabl e | Initial Entry |

090177e196ae2e92\Final\Final On: 01-Apr-2021 03:17 (GMT)