

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: COHORT SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/29/2020 |
|----|--------------|--|

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: DEMOGRAPHY

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 20:43

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [12315081] |
| 2. | Birth Date: | (b) (6)/1957 |
| 3. | Sex: | MALE |
| 4. | Ethnicity: | HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Aug/29/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12315081

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 20:43

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Aug/29/2020 |
| 2. | Phase of Disposition: | SCREENING |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

[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 _____ |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Aug/29/2020 |
| 2. | Weight: | [87.0] |
| 3. | Unit: | kg |
| 4. | Height: | [175.0] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [28.4] |

Vital Signs Details

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Aug/29/2020 |
| 2. | Randomization Number: | [245668] |
| 3. | Randomization Group: | [] |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Aug/29/2020 |
| 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 | [BPTT32] |
| 5.b | Sample ID | [BPTT33] |
| 5.c | Sample ID | [BPTT34] |
| 5.d | Sample ID | [BNTXMB] |
| 5.e | Sample ID | [BNTXMC] |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/29/2020 |
| 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 | [BPWTNF] |
|-----|-----------|----------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12315081

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 20:43

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/29/2020 10:12 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Sep/17/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/17/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [36.8] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/17/2020 |
| 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 | [BPW9YS] |
|-----|-----------|----------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12315081

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 20:43

[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/17/2020 09:26 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Oct/21/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Oct/21/2020 |
| 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 | [BJ5MS9] |
| 5.b | Sample ID | [BKVDVC] |
| 5.c | Sample ID | [BJ4D0D] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Dec/06/2020

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Signs and Symptoms

| | | |
|----|--------------------------------|---|
| 1. | Date of Assessment: | Dec/6/2020 |
| 2. | Date of First Symptom Started: | Dec/4/2020 |
| 3. | Symptoms Ongoing? | NO Date of Last Symptom Resolved: Dec/12/2020 |

Symptoms

| | | |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms: | FEVER |
| | Was symptom present? | YES |
| 4.b | Symptoms: | NEW OR INCREASED COUGH |
| | Was symptom present? | NO |
| 4.c | Symptoms: | NEW OR INCREASED SHORTNESS OF BREATH |
| | Was symptom present? | NO |
| 4.d | Symptoms: | CHILLS |
| | Was symptom present? | YES |
| 4.e | Symptoms: | NEW OR INCREASED MUSCLE PAIN |
| | Was symptom present? | YES |
| 4.f | Symptoms: | NEW LOSS OF TASTE OR SMELL |
| | Was symptom present? | NO |
| 4.g | Symptoms: | NEW OR INCREASED SORE THROAT |
| | Was symptom present? | YES |
| 4.h | Symptoms: | DIARRHEA |
| | Was symptom present? | NO |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | |
|-----|----------------------|----------|
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | NO |

Symptoms - Other

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|------------|--------------------|------------------|------------------------------|---|----------------------------|---------------------------------|
| 1. DELETED | Dec/6/2020 | SWABBED MATERIAL | NASOPHARYNX | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | Repeating Pages |
| 2. | Dec/5/2020 | SWABBED MATERIAL | NASOPHARYNX | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/06/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Deleted, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

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

Microbiology Specimen

| | | | |
|----|-------------------------------|---|--------------------------|
| 1. | Actual Date of Collection: | Dec/6/2020 | |
| 2. | Specimen Type: | SWABBED MATERIAL | |
| 3. | Specimen Collection Location: | NASOPHARYNX | |
| 4. | Assay Code and Description: | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | |
| 5. | Device Type: | SARS-COV-2 DIAGNOSTIC TEST | |
| 6. | Trade Name: | ATILA BIOSYSTEMS IAMP COVID 19 DETECTION KIT | |
| 7. | Test Result: | NEGATIVE | Comments |
| 8. | Comments/Findings/Details: | [] | |
| 9. | Trade Name Other, Specify: | [] | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/06/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Microbiology Specimen

| | | |
|----|-------------------------------|---|
| 1. | Actual Date of Collection: | Dec/5/2020 |
| 2. | Specimen Type: | SWABBED MATERIAL |
| 3. | Specimen Collection Location: | NASOPHARYNX |
| 4. | Assay Code and Description: | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 |
| 5. | Device Type: | SARS-COV-2 DIAGNOSTIC TEST |
| 6. | Trade Name: | OTHER |
| 7. | Test Result: | NEGATIVE |
| 8. | Comments/Findings/Details: | [Sample collected in the Sanatorio Trinidad de Palermo] |
| 9. | Trade Name Other, Specify: | [Unknown] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/06/2020

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Dec/06/2020

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Dec/6/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BPWSW1] |
|-----|-----------|----------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Dec/06/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Health Care Utilization

| | | |
|-----|---------------------------------------|---|
| 1.a | Physician or Healthcare Professional: | SPECIALIST |
| | Occurrence of Visits or Contacts: | NO |
| 1.b | Physician or Healthcare Professional: | EMERGENCY ROOM |
| | Occurrence of Visits or Contacts: | YES Number of Visits or Contacts: [2] |
| 1.c | Physician or Healthcare Professional: | PRIMARY CARE PHYSICIAN |
| | Occurrence of Visits or Contacts: | NO |
| 1.d | Physician or Healthcare Professional: | URGENT CARE |
| | Occurrence of Visits or Contacts: | NO |
| 1.e | Physician or Healthcare Professional: | TELEPHONE CONSULTATION |
| | Occurrence of Visits or Contacts: | NO |
| 1.f | Physician or Healthcare Professional: | OTHER |
| | Occurrence of Visits or Contacts: | NO |

Health Care Utilization Other

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Dec/06/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

Health Care Utilization

| | | |
|----|--|--|
| 3. | Has the subject been hospitalized due to potential COVID-19 illness? | YES Has the subject been in intensive care due to potential COVID-19 illness? NO |
|----|--|--|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Hospitalization Category | Hospitalization Term | Admission Date | Ongoing | Form Instance |
|----|--------------------------|----------------------|----------------|---------|---------------------------------|
| 1. | HOSPITALIZATION STATUS | HOSPITAL | Dec/8/2020 | YES | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS
on Dec/06/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Hospitalization Details

| | | |
|----|---------------------------|------------------------|
| 1. | Hospitalization Category: | HOSPITALIZATION STATUS |
| 2. | Hospitalization Term: | HOSPITAL |
| 3. | Admission Date: | Dec/8/2020 |
| 4. | Ongoing? | YES |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Respiratory Treatment

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Dec/06/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Illness Details

| | | |
|----|--|---|
| 1. | Category of Clinical Event: | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | YES Respiratory Illness Diagnosis: [Left Pyelonephritis] Date of Diagnosis: Dec/12/2020 |
| 3. | Toxicity Grade: | 2 |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Category of Clinical Event: | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance |
|----|-----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. | | | | | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Dec/06/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Illness Details

| | | |
|----|--------------------------------|--|
| 1. | Category of Clinical Event: | |
| 2. | Subcategory of Clinical Event: | |
| 3. | Was a diagnosis obtained? | |
| 4. | Toxicity Grade: | |

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. | | | | | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Dec/06/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Lab Chemistry Details

| | | |
|----|-----------------------------|-----|
| 1. | Lab Panel: | |
| 2. | Laboratory Name and Address | [] |
| 3. | Collection Date: | // |
| 4. | Specimen Type: | |

Lab Result

| | | |
|----|-------------|-----------------------------------|
| 5. | Sponsor ID: | [] |
| | Test: | |
| | Result: | [] |
| | Not Done: | |
| | LNMT | Low [] High [] Unit |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Category for Lab Test | Vendor Name (DERIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-----------------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. | | | | | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/06/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Laboratory Data Hematology

| | | |
|----|-----------------------------|-----|
| 1. | Lab Panel: | |
| 2. | Laboratory Name and Address | [] |
| 3. | Collection Date: | // |
| 4. | Specimen Type: | |

Lab Result

| | | |
|----|-------------|-----------------------------------|
| 5. | Sponsor ID: | [] |
| | Test: | |
| | Result: | [] |
| | Not Done: | |
| | LNMT | Low [] High [] Unit |

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Date: | Vital Signs Details | | | Form Instance |
|----|-------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Dec/06/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

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

Vital Signs Details

| | | |
|----|--|-----|
| 2. | Record Identifier: | |
| | Systolic: | [] |
| | Diastolic: | [] |
| | Respiratory Rate in respirations/minute: | [] |
| | Heart Rate in beats/minute: | [] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Date: | Vital Signs Details | | Form Instance |
|----|-------|---------------------------|--------------------------|---------------------------------|
| 1. | | Record Identifier: | Oxygen Saturation | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Dec/06/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Vital Signs

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

Vital Signs Details

| | | |
|----|-----------------------|-----|
| 2. | Record Identifier: | |
| | SPO2 Pulse Oximetry % | [] |

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | | | | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Dec/06/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Oxygenation Parameters

| | | |
|----|------------------------------------|-----|
| 1. | Date Time of Assessment: | // |
| 2. | Arterial Blood Gases PaO2 (mmHg): | [] |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | [] |

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Dec/06/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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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. | Start Date: | // |
| 6. | Ongoing? | |

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|---|----------------|---|---------------------------------|
| 1. | Dec/5/2020 | CHEST | CT SCAN | NORMAL | Repeating Pages |
| 2. | Dec/8/2020 | OTHER <i>If other, specify:</i> Abdomen | CT SCAN | UNKNOWN | Repeating Pages |
| 3. | Dec/12/2020 | OTHER <i>If other, specify:</i> Abdomen | CT SCAN | ABNORMAL <i>If abnormal, specify findings:</i> Left perirenal fat stranding | Repeating Pages |
| 4. | Dec/12/2020 | CHEST | CT SCAN | UNKNOWN | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

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Imaging

| | | |
|----|-------------------------|------------|
| 1. | Date of Assessment: | Dec/5/2020 |
| 2. | Location of Assessment: | CHEST |
| 3. | Type of Imaging Exam: | CT SCAN |
| 4. | Assessment: | NORMAL |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

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Imaging

| | | |
|----|-------------------------|--|
| 1. | Date of Assessment: | Dec/8/2020 |
| 2. | Location of Assessment: | OTHER If other, specify: [Abdomen] |
| 3. | Type of Imaging Exam: | CT SCAN |
| 4. | Assessment: | UNKNOWN |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Imaging

| | | |
|----|-------------------------|--|
| 1. | Date of Assessment: | Dec/12/2020 |
| 2. | Location of Assessment: | OTHER If other, specify: [Abdomen] |
| 3. | Type of Imaging Exam: | CT SCAN |
| 4. | Assessment: | ABNORMAL If abnormal, specify findings: [Left perirenal fat stranding] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Imaging

| | | |
|----|-------------------------|-------------|
| 1. | Date of Assessment: | Dec/12/2020 |
| 2. | Location of Assessment: | CHEST |
| 3. | Type of Imaging Exam: | CT SCAN |
| 4. | Assessment: | UNKNOWN |

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Jan/04/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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Date of Visit

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

COVID-19 Illness Visit

| | | |
|----|-------------------------|----------|
| 3. | COVID-19 Illness Visit: | COVID_A1 |
|----|-------------------------|----------|

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Jan/04/2021

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BRYSYB] |
| 5.b | Sample ID | [BPTBV0] |
| 5.c | Sample ID | [BRYSZ6] |
| 5.d | Sample ID | [BRYSZ7] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

Unplanned Assessments

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Oct/21/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

Disposition - Follow-Up

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

Date of Visit

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

COVID-19 Repeat Swab

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

Vital Signs

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

Vital Signs Details

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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? | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

Contact Outcome

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

Contact Outcome

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/14/2021 |
| 2. | Erroneous Visit | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

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 20:43

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/19/2021 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER 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 20:43

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Jan/19/2021 |
|----|--------------|--|

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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 _____ |
|----|--|-------------------------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

| | | |
|----|---|--------------------|
| 1. | Date of Completion/Discontinuation /Death : | Jan/19/2021 |
| 2. | Phase of Disposition: | REPEAT SCREENING 1 |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Jan/19/2021 |
| 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 | [BPWBDW] |
| 5.b | Sample ID | [BRYT96] |
| 5.c | Sample ID | [BRYTBW] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Jan/19/2021 |
| 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 | [BPWBGV] |
|-----|-----------|----------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12315081

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 20:43

eCRF Audit Trail History

Vaccination

| | | |
|-----|---|-------------------|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Jan/19/2021 11:35 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Feb/9/2021 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Feb/9/2021 |
| 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 | [BPWD1K] |
|-----|-----------|----------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12315081

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 20:43

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/9/2021 10:38 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Mar/9/2021 |
| 2. | Erroneous Visit | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: CONTACT OUTCOME

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 20:43

[eCRF Audit Trail History](#)

Contact Outcome

| | | |
|----|-------------------|---------------------------------------|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Mar/9/2021 |
| 3. | Comments: | [] |

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

Date of Visit

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12315081

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 20:43

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: 12315081

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 20:43

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: 12315081

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 20:43

Contact Outcome

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

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|---|----------------------|
| 1. | Date of Completion/Discontinuation /Death : | Mar/9/2021 |
| 2. | Phase of Disposition: | OPEN LABEL TREATMENT |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|--|-------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | left pyelonephritis | Dec/4/2020 08:00 | NO End Date Time: Dec/22/2020 20:00 | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | Cavities in left inferior t hird molar | Nov/28/2020 08:00 | NO End Date Time: Dec/3/2020 08:00 | Repeating Pages |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

| | | |
|----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [left pyelonephritis] |
| 4. | Start Date Time: | Dec/4/2020 08:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Dec/22/2020 20:00 |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | |
|-----|--|---|
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [E. Coli infection.] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | 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 | [2020489294] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

| | | |
|----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Cavities in left inferior third molar] |
| 4. | Start Date Time: | Nov/28/2020 08:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Dec/3/2020 08:00 |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | |
|-----|--|--|
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | 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 | [] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1231

Subject No: 12315081

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 20:43

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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 | [] |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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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: | // |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

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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? | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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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? | |

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

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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: 12315081

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 20:43

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Jan/14/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

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: 12315081

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 20:43

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Oct/21/2020 |

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[eCRF Audit Trail History](#)

Casebook Signature Form

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-----------------|-------------------|---|------|--------|
| Tatiana Estrada | Approved | Mar-16-2021 16:46:07 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

Affidavit:

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

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

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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 20:43

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Aug-29-2020 11:29:37 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Aug-29-2020 11:30:09 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Dec/06/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Deleted, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

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| Item | Date | User | Comment |
|------|---|-----------------------------------|---|
| 7 | Dec-15-2020 13:32:37 (UTC-03:00) City of Buenos Aires | Santiago Corradetti (b) (4) | |
| 7 | Dec-12-2020 10:08:37 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) [Redacted] | Swab sample performed exclusively for sponsor. <hr/> Unknown |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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| Item | Date | User | Comment |
|------|---|---------------------|----------------|
| Form | Jan-19-2021 12:37:42 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-----------------|-------------------|---|------|--------|
| Tatiana Estrada | Approved | Mar-16-2021 16:46:07 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

Affidavit:

By my dated signature below, I, TatianaEstrada, 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 12:48:52 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Feb-17-2021 09:17:42 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-09-2021 11:24:31 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12315081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:43**Affidavit:**

N/A

| | | | | |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Jan-21-2021 23:08:45 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Dec-07-2020 18:25:10 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Oct-26-2020 21:43:48 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

Header Text: C4591001

Visit: 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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-29-2020 11:29:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 24 JUL 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Aug-29-2020 11:29:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-29-2020 11:29:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> OBTAINED Date Written Consent Obtained Aug/29/2020 | Initial Entry |

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12315081

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 20:43

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1. Subject ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------|--------------------------------|
| Aug-29-2020 08:57:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12315081 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|------------------------------------|------------------|
| Aug-29-2020 08:57:32 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1957 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-29-2020 11:28:53 (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-29-2020 11:28:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-29-2020 11:28:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-29-2020 11:29:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/29/2020 | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-29-2020 11:29:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/29/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-29-2020 11:29:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------|---------------|
| Aug-29-2020 11:29:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-29-2020 11:30:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/29/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-29-2020 11:30:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 87.0 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-29-2020 11:30:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-29-2020 11:30:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 175.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-29-2020 11:30:57 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:51
Site No: 1231
Subject No: 12315081
Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-29-2020 11:30:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 28.4 | Initial Entry |
|--|-----------------|-------------------------|----------------------------|---------------|

7.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-29-2020 11:30:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier 1 :: Temperature: 36.5 Temperature Unit C : Temperature Loc ation:: ORAL CAVITY | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-29-2020 11:30:57 (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-29-2020 11:30:57 (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-29-2020 11:30:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

7.a Temperature Location:

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-29-2020 11:30:57 (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: 12315081

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 20:43

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-29-2020 11:31:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/29/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-29-2020 11:31:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 245668 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-29-2020 11:31:25 (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-29-2020 11:31:25 (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-31-2020 10:40:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-29-2020 11:31:25 (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-29-2020 11:31:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/29/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Aug-31-2020 10:40:29 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | |
|----------------------------------|---------------------|-------------------|
| (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Sample ID: BPTT32 |
|----------------------------------|---------------------|-------------------|

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-31-2020 10:40:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPTT32 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-31-2020 10:41:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPTT33 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-31-2020 10:41:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPTT33 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-31-2020 10:42:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPTT34 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-31-2020 10:42:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPTT34 | Initial Entry |

5.d

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------------|--|---------------|
| Aug-31-2020 12:05:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Maria del Pilar Pereyra (b) (4) | Data Entry: Sample ID: BNTXMB | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------------|------------------------------|---------------|
| Aug-31-2020 12:05:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Maria del Pilar Pereyra (b) (4) | Data Entry: BNTXMB | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------------|--|---------------|
| Aug-31-2020 12:05:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Maria del Pilar Pereyra (b) (4) | Data Entry: Sample ID: BNTXMC | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------------|------------------------------|---------------|
| Aug-31-2020 12:05:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Maria del Pilar Pereyra (b) (4) | Data Entry: BNTXMC | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-29-2020 11:31:35 (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-29-2020 11:31:35 (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-30-2020 13:39:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-29-2020 11:31:35 (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-29-2020 11:31:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/29/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Aug-30-2020 13:39:58 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1231
Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
Subject No: 12315081
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 20:43

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-30-2020 13:39:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPWTNF | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12315081

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 20:43

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-29-2020 11:31:56 (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-29-2020 11:31:56 (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-29-2020 11:31:56 (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-29-2020 11:31:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/29/2020 10:12 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-29-2020 11:31:56 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:04
Site No: 1231
Subject No: 12315081
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 20:43

| | | | | |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-29-2020 11:31:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |
|--|-----------------|---------------------|----------------------------|---------------|

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-29-2020 11:31:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Aug-29-2020 11:31:56 (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 |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-29-2020 11:31:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12315081

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 20:43

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-29-2020 11:32:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-17-2020 22:30:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/17/2020 | Initial Entry |

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12315081

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 20:43

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Sep-17-2020 22:30:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/17/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Sep-17-2020 22:30:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: Temperature: 36.8 Temperature Unit: Temperature Location: ORAL CAVITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Sep-17-2020 22:30:42 (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-17-2020 22:30:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.8 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Sep-17-2020 22:30:42 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12315081

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 20:43

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

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Sep-17-2020 22:30:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

Header Text: C4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12315081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:43[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-17-2020 11:54:28 (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-17-2020 11:54:28 (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-17-2020 11:54:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-17-2020 11:54:28 (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-17-2020 11:54:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/17/2020 | Initial Entry |

5.a

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

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|---------------------|--|---------------|
| Sep-17-2020 11:54:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPW9YS | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-17-2020 11:54:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPW9YS | Initial Entry |

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12315081

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 20:43

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-17-2020 22:31:07 (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-17-2020 22:31:07 (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-17-2020 22:31:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-17-2020 22:31:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/17/2020 09:26 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-17-2020 22:31:07 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12315081

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 20:43

| | | | | |
|--|-----------------|------------------|----------------------------|---------------|
| Sep-17-2020 22:31:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |
|--|-----------------|------------------|----------------------------|---------------|

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|-------------------------------------|---------------|
| Sep-17-2020 22:31:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|---|---------------|
| Sep-17-2020 22:31:07 (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-17-2020 22:31:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-21-2020 13:14:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/21/2020 | Initial Entry |

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12315081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:43[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-21-2020 13:14:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-21-2020 13:14:40 (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-21-2020 17:58:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-21-2020 13:14:40 (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. |
| Oct-21-2020 13:14:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/21/2020 | Initial Entry |

5.a

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

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|-------------------------|--|---------------|
| Oct-21-2020 17:58:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: Sample ID: BJ5MS9 | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|------------------------------|---------------|
| Oct-21-2020 17:58:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: BJ5MS9 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-21-2020 18:07:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BKVDVC | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-21-2020 18:07:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BKVDVC | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-21-2020 18:25:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BJ4D0D | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-21-2020 18:25:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BJ4D0D | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
on Dec/06/2020 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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-------------------|--|
| Jan-08-2021 16:11:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | Response satisfies query |
| Jan-08-2021 12:36:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Query 4: Answered | Changed data per query |
| Jan-08-2021 09:52:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | According to EMR, subject claimed several tomographies were performed to him on 12DEC2020. Please, consider adding these as separate rows on IMAGING eCRF. Thanks! |
| Dec-14-2020 04:33:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Dec-11-2020 12:04:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | The form was completed. Thank you. |
| Dec-09-2020 14:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | DM: Kindly review and complete 'Illness Details form' at this visit. Thank you. |
| Dec-07-2020 18:28:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
on Dec/06/2020 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:** 12315081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:43

| | | | | |
|--|-----------------|---------------------------|----------------------------------|--|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Dec-07-2020 18:25:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate. |
| Dec-07-2020 18:25:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Dec-07-2020 18:25:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/6/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Dec-07-2020 18:25:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/6/2020 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/4/2020 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---|--|
| Jan-08-2021 12:26:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NO Date of Last Symptom Resolved: Dec/12/2020 | Transcription Error |
| Jan-08-2021 12:25:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NO Date of Last Symptom Resolved: Dec/11/2020 | Due to CT findings, the probable COVID illness was reinterpreted as a SAE (left pyelonephritis) and considered ended on this date. |
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: YES | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

4.a Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.b

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms NEW OR INCREASED COUGH Symptom Present: NO | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.b Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.c Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|-----------------|
| Dec-09-2020 13:42:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: YES | New Information |
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: NO | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.d Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|-----------------|
| Dec-09-2020 13:42:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | New Information |
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom YES Present: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.e Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.f Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.g Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARRHEA Symptom Present NO : | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.h Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMITIN G Symptom Present NO : | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
on Dec/06/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4.i Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-07-2020 18:26:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Dec-07-2020 18:27:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - Other: Headache | Initial Entry |

5.a Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-07-2020 18:27:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Headache | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Dec/06/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

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| Date | Location | User | Value | Reason |
|--|-----------------|--|----------------|---|
| Dec-15-2020 13:38:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Deleted | This Microbiology specimen was uploaded erroneously. It corresponds to the Sponsor's swab. |
| Dec-15-2020 13:36:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Undeleted | I am undeleting the form, just to have the possibility to also delete the "test result" item. |
| Dec-14-2020 11:00:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Deleted | This record was submitted erroneously. This correspond to the sponsor's swab (which is correctly uploaded in the correspondent form). No other microbiology specimen was taken because subject had already been swabbed on 5-DEC. |
| Dec-07-2020 18:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Form Created | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Dec/06/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/06/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Deleted, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Dec-07-2020 18:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/6/2020 | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-07-2020 18:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWABBED MATERIAL | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-07-2020 18:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NASOPHARYNX | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|--|---------------|
| Dec-07-2020 18:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|--|---------------|
| Dec-07-2020 18:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

| 6. Trade Name: | | | | |
|--|-----------------|--------------------------------|--|---|
| Date | Location | User | Value | Reason |
| Dec-07-2020 18:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ATILA BIOSYSTEMS IAMP C OVID-19 DETECTION KIT | Initial Entry |
| 7. Test Result: | | | | |
| Date | Location | User | Value | Reason |
| Dec-16-2020 07:38:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Closed as record is deleted. |
| Dec-15-2020 13:37:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Dec-15-2020 13:37:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NEGATIVE | Initial Entry |
| Dec-15-2020 13:32:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: | Initial Entry |
| Dec-15-2020 03:28:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM : Data is deleted on this form except for Test Result. Thus, Please review and update. Else, clarify. |
| Dec-14-2020 11:00:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | This record was submitted erroneously. This correspond to the sponsor's swab (which is correctly uploaded in the correspondent form). No other microbiology specimen was taken because subject had already been swabbed on 5-DEC. |
| Dec-14-2020 02:56:16 (UTC-03:00) City of | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM1: Please update result once |

| | | | | |
|---|-----------------|------------------|-------------------------------|---|
| Buenos Aires | | | | data is available, until then kindly keep this query in open status. Thank you. |
| Dec-12-2020 10:17:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Result is not available given it was performed exclusively for sponsor |
| Dec-12-2020 10:08:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Unknown | Initial Entry |
| Dec-08-2020 02:25:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: The response for "Results" is missing. Kindly review and update. |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/06/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/5/2020 | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWABBED MATERIAL | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NASOPHARYNX | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|--|---------------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2 | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|--|---------------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/06/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

6. Trade Name:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------|---------------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |

7. Test Result:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

8. Comments/Findings/Details:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------------|
| Dec-09-2020 13:24:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample collected in the Sanatorio o Trinidad de Palermo | Changed Information |
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample collected in the Sanatorio o de la Trinidad de Palermo | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------------|---------------|
| Dec-09-2020 13:24:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Unknown | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/06/2020 - 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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-07-2020 18:28:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Dec-07-2020 18:28:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-07-2020 18:28:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Dec-07-2020 18:28:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample collected by team physician | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History on Dec/06/2020

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|----------------------------|---------------|
| Dec-07-2020 18:28:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|----------------------------------|---------------|
| Dec-07-2020 18:28:16 (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 |
|---|-----------------|------------------------|---------------------------|--|
| Dec-09-2020 11:13:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Dec-08-2020 01:32:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Dec-07-2020 18:28:16 (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. |
| Dec-07-2020 18:28:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History on Dec/06/2020

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | |
|--------------|------------------|---------------------|------------|
| Buenos Aires | (b) (4), (b) (6) | Date of Collection: | Dec/6/2020 |
|--------------|------------------|---------------------|------------|

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|--|---------------|
| Dec-09-2020 11:13:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: Sample ID: BPWSW1 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|------------------------------|---------------|
| Dec-09-2020 11:13:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: BPWSW1 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/06/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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I.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner SPECIA : LIST Occurrence of Visits NO or Contacts: | Initial Entry |

I.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

I.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|-----------------|
| Dec-11-2020 12:05:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENC Y ROOM Occurrence of Visits or Cont acts: YES <i>Number of Vi sits or Conta cts:</i> 2 | New Information |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/06/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|---------------------|--|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |
|--|-----------------|---------------------|--|---------------|

I.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROOM | Initial Entry |

I.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|-----------------|
| Dec-11-2020 12:05:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 2 | New Information |
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

I.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/06/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|--|--|---|--|
| | | | Occurrence of NO Visits or Contacts: | |
|--|--|--|---|--|

I.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

I.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/06/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

1.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

1.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO | Initial Entry |

1.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: TELEPHONE CONSULTATION | Initial Entry |

1.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/06/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

1.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OTHER Occurrence of Visits or NO Contacts: | Initial Entry |

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Dec-09-2020 13:39:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail
on Dec/06/2020

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Dec-09-2020 13:40:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Dec/06/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Hospitalization Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Dec-09-2020 13:40:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: HOSPITALIZATION STATUS | Initial Entry |

2. Hospitalization Term:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-09-2020 13:40:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HOSPITAL | Initial Entry |

3. Admission Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|-----------------|
| Dec-11-2020 12:05:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/8/2020 | New Information |
| Dec-09-2020 13:40:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/5/2020 | Initial Entry |

4. Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|--|
| Dec-11-2020 12:06:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Dec-11-2020 12:06:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | New Information |
| Dec-11-2020 12:05:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Date of current hospital admission is after Date of current hospital |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History on Dec/06/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|---------------------|---|------------------------------|
| | | | | discharge. Please reconcile. |
| Dec-09-2020 13:40:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Discharge Date: Dec/5/2020 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Dec/06/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Dec-11-2020 12:03:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: POTENTIAL COVID-19 ILLNE SS | Initial Entry |

2. Was a diagnosis obtained for Potential COVID-19 Illness?

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--|--------------------------|
| Jan-08-2021 12:26:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Left Pyelonephritis Date of Diagnosis: Dec/12/2020 | New Information |
| Dec-30-2020 18:35:36 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-30-2020 17:45:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Dec-30-2020 17:45:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Perinephritis Date of Diagnosis: Dec/12/2020 | New Information |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Dec/06/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|-------------------------------|--------------------------|---|
| Dec-30-2020 14:55:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Nicole Zalchendler (b) (4) | Query 1: Opened | CRA: please confirm if no diagnosis was obtained for Potential Covid Illnes, as perinephritis diagnosis was confirmed. Thank you. |
| Dec-11-2020 12:03:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Dec-11-2020 12:03:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Dec-09-2020 13:41:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Dec-30-2020 17:48:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Created | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|----------------|--|
| Jan-08-2021 12:30:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Undeleted | I had deleted this CT after a query requested it (it was described in the AE form in our MH). Considering that this CT was key to reach the actual diagnosis of this probable COVID disease, and in response to the new query, I'll undelete it. |
| Jan-06-2021 15:02:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Deleted | Transcription Error |
| Dec-30-2020 17:49:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Created | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Jan-08-2021 12:36:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Created | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|----------------------------------|---|
| Dec-30-2020 18:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-30-2020 17:47:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Dec-30-2020 17:47:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: Dec/5/2020 | Transcription Error |
| Dec-30-2020 15:07:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Nicole Zalchandler (b) (4) | Query 1: Opened | CRA: Per MH, a first chest imaging was performed on 05Dec2020 with a normal result. Please confirm and update accordingly. Thank you! |
| Dec-11-2020 12:09:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/8/2020 | New Information |
| Dec-09-2020 13:41:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/5/2020 | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Dec-09-2020 13:41:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHEST | Initial Entry |

3. Type of Imaging Exam:

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

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|---------------------|-------------------------------|---------------|
| Dec-09-2020 13:41:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CT SCAN | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

4. Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------------|
| Dec-11-2020 12:10:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NORMAL | Transcription Error |
| Dec-11-2020 12:10:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNKNOWN | New Information |
| Dec-09-2020 13:41:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NORMAL | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|----------------------------------|---|
| Jan-07-2021 08:58:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jan-06-2021 14:52:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Query 1: Answered | The CT performed on 8-DEC is mentioned in the MH record written on 11-DEC. Thank you. |
| Jan-06-2021 11:28:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Please reconcile, the date of the CT is not on medical record |
| Dec-30-2020 17:48:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: Dec/8/2020 | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---|---------------|
| Dec-30-2020 17:48:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: OTHER <i>If other, specify:</i> Abdomen | Initial Entry |

3. Type of Imaging Exam:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-------------------------------|---------------|
| Dec-30-2020 17:48:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: CT SCAN | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

4. Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|-------------------------------|---------------|
| Dec-30-2020 17:48:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: UNKNOWN | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Dec/06/2020**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12315081**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:43[Back to Form](#)**1. Date of Assessment:**

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-----------------------------------|--|
| Jan-07-2021 09:02:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jan-06-2021 15:01:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Query 1: Answered | Thank you. I will delete this record, as it is part of the follow-up of the AE "pielonephritis". |
| Jan-06-2021 11:29:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Please reconcile, the date of the CT is not on medical record |
| Dec-30-2020 17:49:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: Dec/12/2020 | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---|---------------------|
| Jan-08-2021 12:31:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: OTHER <i>If other, specify:</i> Abdomen | Changed Information |
| Dec-30-2020 17:49:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: OTHER <i>If other, specify:</i> Chest and abdomen | Initial Entry |

3. Type of Imaging Exam:

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|--------------------------------|-------------------------------|---------------|
| Dec-30-2020 17:49:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: CT SCAN | Initial Entry |
|--|-----------------|--------------------------------|-------------------------------|---------------|

4. Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---|-----------------|
| Jan-08-2021 12:34:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: ABNORMAL <i>If abnormal, specify findings</i> : Left perirenal fat stranding | New Information |
| Jan-08-2021 12:34:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: ABNORMAL <i>If abnormal, specify findings</i> : Perirenal fat stranding | New Information |
| Dec-30-2020 17:49:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: UNKNOWN | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Dec/06/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-----------------------------------|---------------|
| Jan-08-2021 12:36:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: Dec/12/2020 | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-----------------------------|---------------|
| Jan-08-2021 12:36:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: CHEST | Initial Entry |

3. Type of Imaging Exam:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-------------------------------|---------------|
| Jan-08-2021 12:36:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: CT SCAN | Initial Entry |

4. Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-------------------------------|---------------|
| Jan-08-2021 12:36:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: UNKNOWN | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/04/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Jan-04-2021 13:32:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/4/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-04-2021 13:32:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_A1 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/04/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- 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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-04-2021 13:33:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-04-2021 13:33:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|--|
| Jan-05-2021 10:57:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Jan-05-2021 04:50:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-04-2021 13:33:55 (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. |
| Jan-04-2021 13:33:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Visit on Jan/04/2021

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|--|--|------------|--|
| | | | Jan/4/2021 | |
|--|--|--|------------|--|

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Jan-05-2021 10:57:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: Sample ID: BRYSYB | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|------------------------------|---------------|
| Jan-05-2021 10:57:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo (b) (4) | Data Entry: BRYSYB | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Jan-05-2021 11:31:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPTBV0 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Jan-05-2021 11:31:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPTBV0 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Jan-05-2021 11:49:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRYSZ6 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Jan/04/2021 - 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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Jan-05-2021 11:49:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRYSZ6 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Jan-05-2021 11:49:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRYSZ7 | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Jan-05-2021 11:49:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRYSZ7 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-23-2020 08:53:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/21/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-23-2020 08:53:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------|---------------|
| Oct-23-2020 08:53:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-14-2021 14:33:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 | Initial Entry |

Header Text: C4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1231**Subject No:** 12315081**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - 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 20:43[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Jan-14-2021 14:34:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-14-2021 14:33:47 (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. |
| Jan-14-2021 14:33:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-19-2021 12:37:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/19/2021 | Initial Entry |

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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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I. Consent Was:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-19-2021 12:37:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Jan/19/2021 | Initial Entry |

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-19-2021 12:37:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/19/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Jan-19-2021 12:37:54 (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 |
|--|-----------------|---------------------|---------------------------------|---------------|
| Jan-19-2021 12:37:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-19-2021 12:38:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-19-2021 12:38:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|--|
| Jan-20-2021 09:16:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Jan-20-2021 04:47:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-19-2021 12:38:11 (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. |
| Jan-19-2021 12:38:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

Jan/19/2021

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Jan-20-2021 09:16:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPWBDW | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Jan-20-2021 09:16:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPWBDW | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Jan-20-2021 11:03:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRYT96 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Jan-20-2021 11:03:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRYT96 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Jan-20-2021 13:34:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRYTBW | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

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 20:43

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|------------------------------|---------------|
| Jan-20-2021 13:34:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: BRYTBW | 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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-19-2021 12:38:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-19-2021 12:38:20 (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 |
|--|-----------------|---------------------------|--|--|
| Jan-20-2021 12:59:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Jan-20-2021 04:47:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-19-2021 12:38:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-19-2021 12:38:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|--|--|-------------|--|
| | | | Jan/19/2021 | |
|--|--|--|-------------|--|

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-20-2021 12:59:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPWBGV | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-20-2021 12:59:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPWBGV | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12315081

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 20:43

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-19-2021 12:38:52 (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 |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Jan-19-2021 12:38:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Jan-19-2021 12:38:52 (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 |
|--|-----------------|---------------------|---|---------------|
| Jan-19-2021 12:38:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/19/2021 11:35 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-19-2021 12:38:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12315081

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 20:43

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Jan-19-2021 12:38:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-19-2021 12:38:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-19-2021 12:38:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Jan-19-2021 12:38:52 (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 |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-19-2021 12:38:52 (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 |
|--|-----------------|---------------------|---------------------------|---------------|
| Jan-19-2021 12:38:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12315081

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 20:43

Buenos Aires

(b) (4),

(b) (6)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Feb-09-2021 11:24:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/9/2021 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-09-2021 11:24:43 (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-09-2021 11:24:43 (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-10-2021 13:08:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-09-2021 17:55:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-09-2021 11:24:43 (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-09-2021 11:24:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (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: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

Feb/9/2021

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Feb-10-2021 13:08:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPWD1K | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Feb-10-2021 13:08:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPWD1K | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12315081

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 20:43

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-09-2021 11:25:56 (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-09-2021 11:25:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|---------------------------------|---------------|
| Feb-09-2021 11:25:56 (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-09-2021 11:25:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/9/2021 10:38 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|--------------------------------------|---------------|
| Feb-09-2021 11:25:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12315081

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 20:43

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------|---------------|
| Feb-09-2021 11:25:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|-------------------------------------|---------------|
| Feb-09-2021 11:25:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|----------------------------|---------------|
| Feb-09-2021 11:25:56 (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-09-2021 11:25:56 (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-09-2021 11:25:56 (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-09-2021 11:25:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12315081

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 20:43

Buenos Aires

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

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|--|
| Mar-12-2021 15:46:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-12-2021 12:00:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | EOT2 updated |
| Mar-12-2021 11:29:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103. |
| Mar-11-2021 12:48:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/9/2021 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: CONTACT OUTCOME - 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 20:43

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1. Contact Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Mar-11-2021 12:49:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Mar-11-2021 12:49:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Mar/9/2021 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Mar-12-2021 12:00:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/9/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Mar-12-2021 12:00:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: OPEN LABEL TREATMENT | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------|---------------|
| Mar-12-2021 12:00:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

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 20:43

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Form Created | |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-10-2020 13:56:59 (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 |
|--|-----------------|--------------------------------|--------------------------|---|
| Dec-18-2020 19:56:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Thank you so much!! |
| Dec-17-2020 17:56:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Query 1: Answered | I am sorry. The AE ID is automatic and I cannot manually change it. The other AE will be uploaded shortly. |
| Dec-17-2020 15:37:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Apologies! This AE is listed as "2" in medical records, and is listed as "1" in CRF, in addition, please note there is an AE recorded in medical chart: "dolor en tercer molar inferior izquierdo", please add this AE to CRF. Thanks! :) |
| Dec-16-2020 14:46:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Query is ambiguous |
| Dec-16-2020 13:59:11 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CRA: Please not |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|-------------------------|-------------------------|---|
| (UTC-03:00) City of Buenos Aires | | (b) (4), (b) (6) | | this AE is listed as "1" in medical records. Please update accordingly. Thanks! |
| Dec-10-2020 13:56:59 (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 |
|---|-----------------|---------------------------|---|--|
| Jan-08-2021 08:37:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Jan-07-2021 11:01:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | New Information |
| Jan-07-2021 11:01:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: left pyelonephritis | New Information |
| Jan-06-2021 08:46:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON:AER#2020489294, the term in AE CRF was updated to 'perinephritis' while retained as Left pyelonephritis in SDB. Please confirm correct term. If safety update is required, please submit a follow-up form. |
| Dec-17-2020 15:10:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|---|-----------------|------------------|--|--|
| Dec-17-2020 11:32:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: perinephritis | New Information |
| Dec-12-2020 10:13:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | On 12/11/2020 follow up of the SAE was sent. Thank you. |
| Dec-10-2020 19:21:05 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINICAL Please submit a SAE followup with diagnostic information for pyelonephritis, including urinalysis and urine culture lab tests |
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Suspected pyelonephritis | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/4/2020 08:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|-----------------|
| Jan-07-2021 11:02:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Dec/22/2020 20:00 | New Information |
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Dec-10-2020 13:56:59 (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 |
|--|-----------------|---------------------------|---|--|
| Dec-11-2020 07:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Suspected pyelonephritis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Dec-10-2020 13:56:59 (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? | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12315081**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Not Complete**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:43

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

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 13:56:59 (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 |
|--|-----------------|------------------|------------------|---|
| Jan-26-2021 01:10:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Closed | Response satisfies query |
| Jan-22-2021 07:54:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2 : Closed | Closed per site confirmation - same event |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|---|--------------------------------|-----------------------|---|
| Jan-20-2021 11:38:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Query 2 : Answered | E. Coli is the etiology of the pyelonephritis, obtained by urine cultures. I've put that information in response to a previous query. These are not separate diseases, we are talking about the same event. Thank you. |
| Jan-20-2021 07:04:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD (b) (4) | Query 2 : Opened | Please review "If not related to study treatment other" field, the following text was indicated in the comment field [E Coli infection]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4) |
| Jan-15-2021 17:13:46 (UTC-03:00) City of | ACV0PFEINFP6000 | auto query (autoquery) | Query 1 : Answered | New Information |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|------------------|--|---|
| Buenos Aires | | | | |
| Jan-15-2021 17:13:46 (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: OTHER <i>If Other, specify:</i> E. Coli infection. | New Information |
| Jan-13-2021 20:09:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Reissued: Opened | Clinical Thank you. Per CRF Completion guidelines 8.50.8, if event is NOT related |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|--|-----------------|--------------------------------|-----------------------------------|---|
| | | | | to study drug, please indicate what it is due to. In this case E coli is the etiology as you specified. |
| Jan-13-2021 16:53:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Query 1 : Answered | Pyelonephritis is not 'related' to E.Coli infection... E.Coli infection is actually the etiology of the disease. On the other hand, there is no confirmed correlation between renal cysts and a renal infection. Thank you. |
| Jan-13-2021 01:47:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Opened | CLINICAL SAE reports that subject had positive urine culture for E coli; also a history of renal cysts. Please review 'other' reason for Lt. pyelonephritis and update, if appropriate |
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|-------|--|--|---|--|
| Aires | | | If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: unknown | |
|-------|--|--|---|--|

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Dec-10-2020 13:56:59 (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 |
|---|-----------------|------------------|---------------------------|---------------|
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|--|--|
| Jan-07-2021 11:02:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Jan-07-2021 11:02:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | New Information |
| Jan-07-2021 11:02:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | For AE left pyelonephritis: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present. |
| Jan-02-2021 04:57:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Outcome updated SDB.issue resolved |
| Dec-22-2020 10:14:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Candidate | Pending SDB update |
| Dec-18-2020 10:47:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Follow-up form was sent. The adverse event is not recovered. |
| Dec-17-2020 09:18:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | SAE RECON:AER#2020489294,outcome was reported as |

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

| | | | | |
|---|-----------------|------------------|---|--|
| of Buenos Aires | | | | RECOVERED/RESOLVED to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form. |
| Dec-10-2020 13:56:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED /NOT RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 13:56:59 (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 |
|--|-----------------|------------------|----------------------------------|---------------|
| Dec-11-2020 07:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020489294 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12315081**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:43[Back to Form](#)**1. Category:**

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-17-2020 17:59:46 (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 |
|--|-----------------|-------------------------|-------------------------|--|
| Dec-23-2020 12:24:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Query raised for the wrong field |
| Dec-23-2020 12:15:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | As per EMR Adverse Event tab (note from 08Dec2020), the diagnose for "Left inferior third molar pain" was cavities. As per CRFG 7.0, when listing an AE, record diagnosis not symptom. Please review the CRF and amend if necessary. |
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|-----------------|--------------------|
| Dec-24-2020 16:57:22 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies |

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12315081**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:43

| | | | | |
|--|-----------------|--------------------------------|---|--|
| (UTC-03:00) City of Buenos Aires | | (b) (4), (b) (6) | | query |
| Dec-24-2020 11:04:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Dec-24-2020 11:04:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: Cavities in left inferior third molar | Changed Information |
| Dec-23-2020 12:24:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | As per EMR Adverse Event tab (note from 08Dec2020), the diagnose for "Left inferior third molar pain" was cavities. As per CRFG 7.0, when listing an AE, record diagnosis not symptom. Please review the CRF and amend if necessary. |
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: Left inferior third molar pain | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: Nov/28/2020 08:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NO End Date Time: | Initial Entry |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

Dec/3/2020 08:00

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|-------------------------|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | 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 |
|--|-----------------|--------------------------------|--------------------------|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NO | Initial Entry |

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

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

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--------------------------|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------|--------------------------|
| Dec-28-2020 15:18:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-24-2020 11:03:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12315081**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:43

| | | | | |
|--|-----------------|--------------------------------|--|---|
| Dec-24-2020 11:03:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown | Changed Information |
| Dec-23-2020 12:27:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Depending on the query result raised on 23dec2020 for field 2 "Adverse Event Term", please review this field. |
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Cavities | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--------------------------------------|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---------------------------|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: YES | Initial Entry |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---------------------------|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | 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 |
|--|-----------------|--------------------------------|--------------------------|---------------|
| Dec-17-2020 17:59:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti (b) (4) | Data Entry: NO | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

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 20:43

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-14-2021 14:34:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-14-2021 14:34:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12315081

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:43

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1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Oct-23-2020 08:53:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Aug-29-2020 11:31:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-29-2020 11:29:54 (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-23-2020 08:53:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/21/2020 | Initial Entry |
| Aug-29-2020 11:31:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/29/2020 | Initial Entry |
| Aug-29-2020 11:29:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/29/2020 | Initial Entry |

090177e196ae2e77\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12315081

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:43

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1. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-26-2020 21:43:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |