

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[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:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Aug/26/2020 |
|----|--------------|--|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [12314134]                                 |
| 2. | Birth Date:                     | (b) (6)/1978                               |
| 3. | Sex:                            | FEMALE                                     |
| 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:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Aug/26/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Aug/26/2020 |
| 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:** 12314134

**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 20:34

**Form Comments**

**Medical History Details**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Aug/26/2020 |
| 2. | Weight:          | [59.0]      |
| 3. | Unit:            | kg          |
| 4. | Height:          | [158.0]     |
| 5. | Unit:            | cm          |
| 6. | Body Mass Index: | [23.6]      |

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 7.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.8]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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 20:34

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Aug/26/2020  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     | NEGATIVE                      |
|     | Not Done:   |                               |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Aug/26/2020 |
| 2. | Randomization Number: | [67400]     |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Aug/26/2020 |
| 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 | [BNTY7M] |
| 5.b | Sample ID | [BNTY7N] |
| 5.c | Sample ID | [BNTY7P] |
| 5.d | Sample ID | [BPT9FC] |
| 5.e | Sample ID | [BPT9FD] |
| 5.f | Sample ID | [BPT9FF] |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Aug/26/2020 |
| 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 | [BP2FFD] |
|-----|-----------|----------|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[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/26/2020 11:40                         |
| 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                                       |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Sep/14/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Sep/14/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [37.6]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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 20:34

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Sep/14/2020  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     | NEGATIVE                      |
|     | Not Done:   |                               |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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

**Electronic Sample Tracking**

|    |  |                |                          |
|----|--|----------------|--------------------------|
| 1. | Data Origin  |                |                          |
| 2. | Sample Type  |                |                          |
| 3. | Sample Collected?  | Not Applicable | <a href="#">Comments</a> |
| 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 | [BP2FFD] |
|-----|-----------|----------|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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

**Vaccination**

|     |   |                          |                          |
|-----|---|--------------------------|--------------------------|
| 1.  | Was there a temporary delay of vaccination?   | Not Done<br>_____        | <a href="#">Comments</a> |
| 2.  | Treatment Name  | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 3.  | Formulation:  | Not Done<br>_____        | <a href="#">Comments</a> |
| 4.  | Dose Date Time:   | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 5.  | Anatomical Location:  | Not Done<br>_____        | <a href="#">Comments</a> |
| 6.  | Body Side:  | Not Done<br>_____        | <a href="#">Comments</a> |
| 7.  | Route:  | Not Done<br>_____        | <a href="#">Comments</a> |
| 8.  | Actual Dose:  | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 9.  | Unit:   | Not Done<br>_____        | <a href="#">Comments</a> |
| 10. | Timeframe Subject Was Observed  | Not Done<br>_____        | <a href="#">Comments</a> |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | Not Done<br>_____        | <a href="#">Comments</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Oct/12/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Oct/12/2020 |
| 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 | [BRXTR1] |
| 5.b | Sample ID | [BRXTRH] |
| 5.c | Sample ID | [BPT7JB] |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Sep/3/2020 |
| 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 Sep/03/2020

**Form Version:** 21-Aug-2020 02:52

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Signs and Symptoms**

|    |                                |             |
|----|--------------------------------|-------------|
| 1. | Date of Assessment:            | Sep/3/2020  |
| 2. | Date of First Symptom Started: | Aug/27/2020 |
| 3. | Symptoms Ongoing?              | NO          |
|    | Date of Last Symptom Resolved: | Sep/25/2020 |

**Symptoms**

|     |                      |                                      |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms:            | FEVER                                |
|     | Was symptom present? | YES                                  |
| 4.b | Symptoms:            | NEW OR INCREASED COUGH               |
|     | Was symptom present? | YES                                  |
| 4.c | Symptoms:            | NEW OR INCREASED SHORTNESS OF BREATH |
|     | Was symptom present? | NO                                   |
| 4.d | Symptoms:            | CHILLS                               |
|     | Was symptom present? | NO                                   |
| 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? | NO                                   |
| 4.h | Symptoms:            | DIARRHEA                             |
|     | Was symptom present? | NO                                   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Sep/03/2020

**Form Version:** 21-Aug-2020 02:52

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Symptoms - Other**

|     |                        |                  |
|-----|------------------------|------------------|
| 5.a | Symptoms - Other Text: | [headache]       |
| 5.b | Symptoms - Other Text: | [rhinorrhea]     |
| 5.c | Symptoms - Other Text: | [ABDOMINAL PAIN] |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date of Collection | Specimen Type    | Specimen Collection Location | Assay Code and Description                      | Device Type                | Form Instance                   |
|----|--------------------|------------------|------------------------------|---|----------------------------|---------------------------------|
| 1. | Sep/3/2020         | SWABBED MATERIAL | NASOPHARYNX                  | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | <a href="#">Repeating Pages</a> |
| 2. | Aug/28/2020        | SWABBED MATERIAL | NASOPHARYNX                  | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | <a href="#">Repeating Pages</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Microbiology Specimen**

|    |                               |  |
|----|-------------------------------|--|
| 1. | Actual Date of Collection:    | Sep/3/2020                                   |
| 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                                     |
| 8. | Comments/Findings/Details:    | [ ]  |
| 9. | Trade Name Other, Specify:    | [ ]  |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Sep/03/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Microbiology Specimen**

|    |                               |   |
|----|-------------------------------|---|
| 1. | Actual Date of Collection:    | Aug/28/2020   |
| 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:                   | CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL   |
| 7. | Test Result:                  | POSITIVE  |
| 8. | Comments/Findings/Details:    | [Swab material collected in Htal Municipal de Trauma y Emergencias Dr. Federico Abete. Pablo Nogues. Malvinas Argentinas. Buenos Aires] |
| 9. | Trade Name Other, Specify:    | [ ]   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/03/2020

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

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | NASAL_SWAB                               |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Sep/3/2020 |
| 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 | [BP2D27] |
|-----|-----------|----------|

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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Sep/03/2020**Form Version:** 15-Sep-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:** 12314134**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[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<br>Number of Visits or Contacts:<br>[1] |
| 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**

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

**Health Care Utilization**

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

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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?                                      |     |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Sep/03/2020

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

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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<br>Respiratory Illness Diagnosis:<br>[Covid 19 disease]<br><br>Date of Diagnosis:<br>Aug/28/2020 |
| 3. | Toxicity Grade:  | 1  |

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**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Category of Clinical Event | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance                   |
|----|----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. |                            |                               |                    |                | <a href="#">Repeating Pages</a> |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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 Version:** 21-Aug-2020 02:49

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result                 |       |         | Form Instance                   |
|----|-----------------------|-------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. |                       |             |                  |               | Sponsor-Defined Identifier | Test: | Result: | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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<br>[ ]<br>High<br>[ ]<br>Unit |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Category for Lab Test | Vendor Name (DE RIVED) | Collection Date: | Specimen Type | Lab Result                 |       |         | Form Instance                   |
|----|-----------------------|------------------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. |                       |                        |                  |               | Sponsor-Defined Identifier | Test: | Result: | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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<br>[ ]<br>High<br>[ ]<br>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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date: | Vital Signs Details       |                  |                   | Form Instance                   |
|----|-------|---------------------------|------------------|-------------------|---------------------------------|
| 1. |       | <b>Record Identifier:</b> | <b>Systolic:</b> | <b>Diastolic:</b> | <a href="#">Repeating Pages</a> |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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:              | [ ] |

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date: | Vital Signs Details |                   | Form Instance                   |
|----|-------|---------------------|-------------------|---------------------------------|
| 1. |       | Record Identifier:  | Oxygen Saturation | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance                   |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. |                         |                           |                                   | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Concomitant Medications**

|    |   |     |
|----|---|-----|
| 1. | What is the medication identifier?  | [ ] |
| 2. | Category:   |     |
| 3. | Concomitant Medications<br>Pre-specified:   |     |
| 4. | Medication:<br><br>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [ ] |
| 5. | 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:** 12314134 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance                   |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | Sep/13/2020        | CHEST                  | X-RAY          | NORMAL             | <a href="#">Repeating Pages</a> |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Imaging**

|    |                         |             |
|----|-------------------------|-------------|
| 1. | Date of Assessment:     | Sep/13/2020 |
| 2. | Location of Assessment: | CHEST       |
| 3. | Type of Imaging Exam:   | X-RAY       |
| 4. | Assessment:             | NORMAL      |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/24/2020 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Dec/24/2020

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Signs and Symptoms**

|    |                                |             |
|----|--------------------------------|-------------|
| 1. | Date of Assessment:            | Dec/24/2020 |
| 2. | Date of First Symptom Started: | Dec/16/2020 |
| 3. | Symptoms Ongoing?              | NO          |
|    | Date of Last Symptom Resolved: | Dec/25/2020 |

**Symptoms**

|     |                      |                                      |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms:            | FEVER                                |
|     | Was symptom present? | NO                                   |
| 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? | NO                                   |
| 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                                   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Dec/24/2020

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Symptoms - Other**

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

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date of Collection | Specimen Type    | Specimen Collection Location | Assay Code and Description                      | Device Type                | Form Instance                   |
|----|--------------------|------------------|------------------------------|---|----------------------------|---------------------------------|
| 1. | Dec/24/2020        | SWABBED MATERIAL | NASOPHARYNX                  | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | <a href="#">Repeating Pages</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Dec/24/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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[Form Audit Trail](#)

**Microbiology Specimen**

|    |                               |  |
|----|-------------------------------|--|
| 1. | Actual Date of Collection:    | Dec/24/2020                                  |
| 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                                     |
| 8. | Comments/Findings/Details:    | [ ]  |
| 9. | Trade Name Other, Specify:    | [ ]  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

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

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[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 a team physician] |

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPW8DL] |
|-----|-----------|----------|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[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:     | NO                     |
| 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**

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

**Health Care Utilization**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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?                                      |     |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Illness Details**

|    |  |  |
|----|--|--|
| 1. | Category of Clinical Event:                              | POTENTIAL COVID-19 ILLNESS   |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | YES<br>Respiratory Illness Diagnosis:<br>[Upper airway catarrh]<br><br>Date of Diagnosis:<br>Dec/26/2020 |
| 3. | Toxicity Grade:  | 1  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Category of Clinical Event | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance                   |
|----|----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. |                            |                               |                    |                | <a href="#">Repeating Pages</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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 2

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result                 |       |         | Form Instance                   |
|----|-----------------------|-------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. |                       |             |                  |               | Sponsor-Defined Identifier | Test: | Result: | <a href="#">Repeating Pages</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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<br>[ ]<br>High<br>[ ]<br>Unit |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Category for Lab Test | Vendor Name (DE RIVED) | Collection Date: | Specimen Type | Lab Result                 |       |         | Form Instance                   |
|----|-----------------------|------------------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. |                       |                        |                  |               | Sponsor-Defined Identifier | Test: | Result: | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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<br>[ ]<br>High<br>[ ]<br>Unit |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date: | Vital Signs Details       |                  |                   | Form Instance                   |
|----|-------|---------------------------|------------------|-------------------|---------------------------------|
| 1. |       | <b>Record Identifier:</b> | <b>Systolic:</b> | <b>Diastolic:</b> | <a href="#">Repeating Pages</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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:              | [ ] |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date: | Vital Signs Details |                   | Form Instance                   |
|----|-------|---------------------|-------------------|---------------------------------|
| 1. |       | Record Identifier:  | Oxygen Saturation | <a href="#">Repeating Pages</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance                   |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. |                         |                           |                                   | <a href="#">Repeating Pages</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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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 2

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Concomitant Medications**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance                   |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. |                    |                        |                |                    | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit    **Form:** IMAGING  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Imaging**

|    |                         |    |
|----|-------------------------|----|
| 1. | Date of Assessment:     | // |
| 2. | Location of Assessment: |    |
| 3. | Type of Imaging Exam:   |    |
| 4. | Assessment:             |    |

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/06/2020

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

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Illness Visit**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/06/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP1VPG] |
| 5.b | Sample ID | [BNV5ZC] |
| 5.c | Sample ID | [BNV5ZS] |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/28/2021

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

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/28/2021 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

|    |                         |          |
|----|-------------------------|----------|
| 3. | COVID-19 Illness Visit: | COVID_B1 |
|----|-------------------------|----------|

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/28/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jan/28/2021 |
| 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 | [BRYWL5] |
| 5.b | Sample ID | [BRYWL6] |
| 5.c | Sample ID | [BPWFGX] |
| 5.d | Sample ID | [BRYWHC] |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Unplanned Assessments**

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

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** DISPOSITION - TREATMENT

**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 20:34

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |  |  |
|----|--|--|
| 1. | Date of Completion/Discontinuation/Death : | Sep/14/2020  |
| 2. | Phase of Disposition:                      | VACCINATION  |
| 3. | Status:                                    | NO LONGER MEETS ELIGIBILITY CRITERIA                         |
| 4. | Specify Status:                            | [Previous clinical or microbiological diagnosis of COVID-19] |

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

**Disposition - Follow-Up**

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Lab Urinalysis**

|    |                                       |     |
|----|---------------------------------------|-----|
| 1. | Lab Panel:                            |     |
| 2. | Lab Sub-Panel:                        |     |
| 3. | Collection Date:                      | //  |
| 4. | Laboratory Name and Address (Derived) | [ ] |
| 5. | Specimen Type:                        |     |

**Lab Result**

|    |             |     |
|----|-------------|-----|
| 6. | Sponsor ID: | [ ] |
|    | Test:       |     |
|    | Result:     |     |
|    | Not Done:   |     |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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? |     |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3<br><br>Participant is:<br>eligible per other protocol allowance(s) 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:** 12314134

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

**Form:** DATE OF VISIT

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Mar/23/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**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 20:34

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Mar/23/2021 |
|----|--------------|--|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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 |
|----|--|----------------|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**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 20:34

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

|    |  |                    |
|----|--|--------------------|
| 1. | Date of Completion/Discontinuation/Death : | Mar/23/2021        |
| 2. | Phase of Disposition:                      | REPEAT SCREENING 1 |
| 3. | Status:                                    | COMPLETED          |
| 4. | Specify Status:                            | [ ]                |

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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 20:34

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Mar/23/2021  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     | NEGATIVE                      |
|     | Not Done:   |                               |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Mar/23/2021 |
| 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 | [BS1R5C] |
| 5.b | Sample ID | [BS1PZJ] |
| 5.c | Sample ID | [BP1X4W] |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314134

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

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

**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 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Mar/23/2021 |
| 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 | [BRN0V1] |
|-----|-----------|----------|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION

**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 20:34

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |                   |
|-----|---|-------------------|
| 1.  | Was there a temporary delay of vaccination?   | NO                |
| 2.  | Treatment Name  | [BNT162b2]        |
| 3.  | Formulation:  | INJECTION         |
| 4.  | Dose Date Time:   | Mar/23/2021 11:11 |
| 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               |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

**Lab Urinalysis**

|    |                                       |     |
|----|---------------------------------------|-----|
| 1. | Lab Panel:                            |     |
| 2. | Lab Sub-Panel:                        |     |
| 3. | Collection Date:                      | //  |
| 4. | Laboratory Name and Address (Derived) | [ ] |
| 5. | Specimen Type:                        |     |

**Lab Result**

|    |             |     |
|----|-------------|-----|
| 6. | Sponsor ID: | [ ] |
|    | Test:       |     |
|    | Result:     |     |
|    | Not Done:   |     |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314134

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

**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? |     |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

**Contact Outcome**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

**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:** 12314134

**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 20:34

**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:** 12314134

**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 20:34

**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:** Not Started

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Disposition - Treatment**

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

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| #  | Category      | AE Identifier | Adverse Event          | Start Date        | Is the Adverse Event Still Ongoing              | Form Instance                   |
|----|---------------|---------------|------------------------|-------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1             | Drug Exposed Pregnancy | Dec/7/2020 08:00  | NO<br>End Date Time:<br><br>Feb/13/2021 UNK:UNK | <a href="#">Repeating Pages</a> |
| 2. | ADVERSE EVENT | 2             | incomplete abortion    | Feb/11/2021 09:00 | NO<br>End Date Time:<br><br>Feb/13/2021 19:00   | <a href="#">Repeating Pages</a> |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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[Form Audit Trail](#)

**Adverse Event Report**

|    |   |  |                          |
|----|---|--|--------------------------|
| 1. | Category:   | ADVERSE EVENT  |                          |
| 2. | AE ID:  | [1]  |                          |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Drug Exposed Pregnancy]   |                          |
| 4. | Start Date Time:  | Dec/7/2020 08:00   |                          |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Feb/13/2021 UNK:UNK  |                          |
| 6. | Toxicity Grade:   | Not Applicable   | <a href="#">Comments</a> |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO   |                          |
| 8. | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log.   | NO   |                          |
| 9. | Is this event related to study treatment:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[unknown] |                          |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Adverse Event Report**

|    |   |  |
|----|---|--|
| 1. | Category:   | ADVERSE EVENT  |
| 2. | AE ID:  | [2]  |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [incomplete abortion]  |
| 4. | Start Date Time:  | Feb/11/2021 09:00  |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Feb/13/2021 19:00  |
| 6. | Toxicity Grade:   | 3  |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES<br><br>Is this serious event associated with congenital anomaly or birth defect?<br>NO<br><br>Did this serious event result in death?<br>NO<br><br>Did this serious event require or prolong hospitalization?<br>YES<br><br>Did this serious event result in persistent or significant disability/incapacity?<br>NO<br><br>Is this serious event life threatening?<br>NO<br><br>Other medically important serious event<br>YES |
| 8. | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log.   | NO   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

|     |  |  |
|-----|--|--|
| 9.  | Is this event related to study treatment:                                  | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[it is 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:<br>For Pfizer Use Only                       | [2021024046]   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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**Medication Error**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Concomitant Medications**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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**Concomitant Medications**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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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:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Mar/19/2021                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

**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:** 12314134

**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 20:34

**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:** 12314134

**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 20:34

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |              |
|----|---------------------|--------------|
| 1. | Subject Status      | DISCONTINUED |
| 2. | Subject Status Date | Sep/14/2020  |

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

| Name | Signature Meaning | Date | Type | Action |
|------|-------------------|------|------|--------|
|------|-------------------|------|------|--------|

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| Form | Aug-26-2020 13:11:42 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| Form | Aug-26-2020 13:12:11 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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| Item | Date  | User                | Comment         |
|------|---|---------------------|-----------------|
| Form | Oct-23-2020 08:27:25 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Applicable. |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
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 20:34

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| 3    | Oct-21-2020 09:57:00 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| Form | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 1    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 2    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 3    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 4    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 5    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 6    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 7    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 8    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 9    | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 10   | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** VACCINATION - 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 20:34

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| Item | Date  | User                | Comment  |
|------|---|---------------------|----------|
| 11   | Oct-04-2020 14:37:32 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| Form | Mar-23-2021 16:52:56 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ADVERSE EVENT REPORT - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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| Item | Date  | User                           | Comment        |
|------|---|--------------------------------|----------------|
| 6    | Jan-19-2021 15:08:31 (UTC-03:00) City of Buenos Aires | Santiago Corradetti<br>(b) (4) | Not Applicable |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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

- CRF\_Sign
- CRF\_Sign\_1

| Name    | Signature Meaning | Date  | Type | Action                            |
|---------|-------------------|---|------|-----------------------------------|
| (b) (6) | N/A               | Mar-23-2021 16:50:25 (UTC-03:00) City of Buenos Aires |      | Edit - All signatures invalidated |

**Affidavit:**

N/A

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Mar-23-2021 12:44:38 (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.

|                 |     |   |  |                                   |
|-----------------|-----|---|--|-----------------------------------|
| Martina Davalli | N/A | Mar-20-2021 10:28:36 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|-----------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Mar-19-2021 17:14:26 (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.

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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, Verified

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-10-2021 12:50:17 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Jan-29-2021 14:51:10 (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 | Jan-28-2021 12:12:37 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Jan-22-2021 11:16:01 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|---|------|--------|

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Dec-27-2020 10:04:33 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314134**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Nov-13-2020 18:51:16 (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 | Nov-12-2020 10:56:09 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Nov-03-2020 12:34:19 (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 | Nov-02-2020 12:32:42 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Oct-23-2020 17:07:01 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|---|------|--------|

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** CASEBOOK SIGNATURE FORM - Signature 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 20:34

**Affidavit:**

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

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

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

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314134

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 13:11:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>24 JUL 2020 | Initial Entry |

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

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Aug-26-2020 13:11:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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***1. Consent Was:***

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 13:11:20<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Aug/26/2020 | Initial Entry |

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314134

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 20:34

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**1. Subject ID**

| Date   | Location        | User                    | Value                          | Reason                         |
|--|-----------------|-------------------------|--------------------------------|--------------------------------|
| Aug-26-2020 10:20:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>12314134 | Item copied from previous form |

**2. Birth Date:**

| Date   | Location        | User                    | Value                              | Reason           |
|--|-----------------|-------------------------|------------------------------------|------------------|
| Aug-26-2020 10:20:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6)/1978 | Enrollment Entry |

**3. Sex:**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-26-2020 13:11:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FEMALE | Initial Entry |

**4. Ethnicity:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-26-2020 13:11:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>HISPANIC OR LATINO(A) OR O<br>F SPANISH ORIGIN | Initial Entry |

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

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-26-2020 13:11:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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*I. Date of Visit*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 13:11:31<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Aug/26/2020 | Initial Entry |



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 13:12:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Aug/26/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-26-2020 13:12:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Aug-26-2020 13:12:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314134

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 20:34

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**1. Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Aug/26/2020 | Initial Entry |

**2. Weight:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>59.0 | Initial Entry |

**3. Unit:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>kg | Initial Entry |

**4. Height:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>158.0 | Initial Entry |

**5. Unit:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>cm | Initial Entry |

**6. Body Mass Index:**

| Date                 | Location        | User      | Value              | Reason        |
|----------------------|-----------------|-----------|--------------------|---------------|
| Aug-26-2020 13:12:52 | ACV0PFEINFP6000 | auto calc | <u>Data Entry:</u> | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314134

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 20:34

|                                  |  |            |      |  |
|----------------------------------|--|------------|------|--|
| (UTC-03:00) City of Buenos Aires |  | (autocalc) | 23.6 |  |
|----------------------------------|--|------------|------|--|

7.a

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Record Identifier:: 1<br>Temperature: 36.8<br>Temperature Unit: C<br>Temperature Locat ORAL CAVI<br>ion:: TY | Initial Entry |

7.a Record Identifier:

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

7.a Temperature:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>36.8 | Initial Entry |

7.a Unit:

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

7.a Temperature Location:

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 13:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1231**Subject No:** 12314134**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - 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 20:34[Back to Form](#)**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Aug-26-2020 13:13:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-26-2020 13:13:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

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

**4. Laboratory Name and Address (Derived)**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Aug-26-2020 13:13:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Aug-26-2020 13:13:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

**6.a**

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

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

|  |                 |                         |   |               |
|--|-----------------|-------------------------|---|---------------|
| Aug-26-2020 13:13:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin in Beta_PX113<br><b>Result::</b> NEGATIVE<br><b>Not Done::</b> | Initial Entry |
|--|-----------------|-------------------------|---|---------------|

6.a Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Aug-26-2020 13:13:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

6.a Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-26-2020 13:13:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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**1. Randomization Date :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 13:13:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Aug/26/2020 | Initial Entry |

**2. Randomization Number:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-26-2020 13:13:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>67400 | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-26-2020 13:13:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Aug-26-2020 13:13:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Aug-27-2020 13:44:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed   | Close Auto Query   |
| Aug-26-2020 14:26:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-26-2020 13:13:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-26-2020 13:13:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/26/2020 | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

5.a

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Aug-27-2020 13:44:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BNTY7M</b> | Initial Entry |

5.a Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Aug-27-2020 13:44:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BNTY7M | Initial Entry |

5.b

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Aug-27-2020 13:45:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BNTY7N</b> | Initial Entry |

5.b Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Aug-27-2020 13:45:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BNTY7N | Initial Entry |

5.c

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Aug-27-2020 13:45:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BNTY7P</b> | Initial Entry |

5.c Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Aug-27-2020 13:45:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BNTY7P | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

5.d

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Aug-27-2020 18:36:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BPT9FC | Initial Entry |

5.d Sample ID

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Aug-27-2020 18:36:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br>BPT9FC | Initial Entry |

5.e

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Aug-27-2020 18:36:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BPT9FD | Initial Entry |

5.e Sample ID

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Aug-27-2020 18:36:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br>BPT9FD | Initial Entry |

5.f

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Aug-27-2020 18:36:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BPT9FF | Initial Entry |

5.f Sample ID

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Aug-27-2020 18:36:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br>BPT9FF | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-26-2020 13:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Aug-26-2020 13:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Sep-04-2020 18:03:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed   | Close Auto Query   |
| Aug-26-2020 14:26:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-26-2020 13:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-26-2020 13:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/26/2020 | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.a**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Sep-04-2020 18:03:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BP2FFD | Initial Entry |

**5.a Sample ID**

| Date   | Location                                  | User                    | Value                        | Reason  |
|--|---|-------------------------|------------------------------|---|
| Sep-07-2020 15:58:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)    | Query 1: Closed              | Auto closed by Validation Check: VC_BEETRK001_01  |
| Sep-07-2020 13:36:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)        | Query 1: Answered            | Original value is correct   |
| Sep-04-2020 22:22:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)    | Query 1: Opened              | DMW4621235;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate. |
| Sep-04-2020 18:03:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br>BP2FFD | Initial Entry   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314134

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 20:34

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-26-2020 13:13:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-26-2020 13:13:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-26-2020 13:13:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-26-2020 13:13:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Aug/26/2020 11:40 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-26-2020 13:13:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date                 | Location        | User             | Value              | Reason        |
|----------------------|-----------------|------------------|--------------------|---------------|
| Aug-26-2020 13:13:59 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**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 No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**7. Route:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-26-2020 13:13:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Aug-26-2020 13:13:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OBSERVATION PERIOD | Initial Entry |

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

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-26-2020 13:13:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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*1. Select appropriate response - Reactogenicity diary collection*

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 13:14:07<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT | Initial Entry |

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314134

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 20:34

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*I. Date of Visit*

| Date   | Location        | User             | Value                             | Reason   |
|--|-----------------|------------------|-----------------------------------|--|
| Oct-20-2020 06:02:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed                   | EOT updated  |
| Oct-20-2020 06:01:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened                   | DM: Kindly consider to update missing SWAB PFE form or else clarify. Thank you.  |
| Oct-05-2020 05:04:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed                   | Response satisfies query   |
| Oct-04-2020 14:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered                 | The form level "Not Done" was added.   |
| Sep-29-2020 08:38:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened          | DM1: Thanks for your response. As per completion guidelines section 4.10, please consider to add form level 'Not Done' comment to Vaccination form; Else, clarify. |
| Sep-28-2020 11:14:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered                 | This subject was discontinued before finishing the visit process.  |
| Sep-26-2020 12:16:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened                   | DM: Kindly review and complete 'Vaccination form' at this visit. Thank you.  |
| Sep-18-2020 01:20:28<br>(UTC-03:00) City of              | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sep/14/2020 | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

Buenos Aires

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314134

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 20:34

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**1. Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-18-2020 01:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/14/2020 | Initial Entry |

**2.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-18-2020 01:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier 1</b><br>:<br><b>Temperature:</b> 37.6<br><b>Temperature Unit:</b><br><b>Temperature Location:</b> ORAL CAVITY | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-18-2020 01:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date   | Location        | User                      | Value             | Reason   |
|--|-----------------|---------------------------|-------------------|--|
| Sep-22-2020 09:22:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Closed   | Response satisfies query                           |
| Sep-21-2020 12:02:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Answered | Original value is correct                          |
| Sep-18-2020 01:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened   | Temperature 37.6 C is outside of Normal Range 36.1 |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

|  |                 |                     |                            |               |
|--|-----------------|---------------------|----------------------------|---------------|
|  |                 |                     |                            | - 37.5 C.     |
| Sep-18-2020 01:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>37.6 | Initial Entry |

**2.a Unit:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-18-2020 01:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

**2.a Temperature Location:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-18-2020 01:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/14/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

**6.a**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b> NEGATIVE<br><b>Not Done::</b> | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

6.a Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX1<br>13 | Initial Entry |

6.a Result:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-18-2020 01:21:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEGATIVE | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason              |
|--|-----------------|-------------------------|----------------------------|---------------------|
| Sep-14-2020 11:24:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b>         | Transcription Error |
| Aug-27-2020 09:27:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry       |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason              |
|--|-----------------|-------------------------|----------------------------------|---------------------|
| Sep-14-2020 11:24:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b>               | Transcription Error |
| Aug-27-2020 09:27:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry       |

**3. Sample Collected?**

| Date   | Location        | User             | Value             | Reason  |
|--|-----------------|------------------|-------------------|---|
| Oct-23-2020 12:03:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Closed   | Response satisfies query  |
| Oct-23-2020 12:03:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Closed   | Response satisfies query  |
| Oct-23-2020 08:29:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Answered | The patient was discontinued due to acute illness, suspected of COVID-19, for this reason no nasal swab |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

|  |   |                      |                                       |   |
|--|---|----------------------|---------------------------------------|---|
|  |   |                      |                                       | sample was taken.   |
| Oct-23-2020<br>08:27:45<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | Query 5: Answered                     | Changed data per query  |
| Oct-22-2020<br>05:53:06<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4) | Query 6: Opened                       | DMW5123200;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify    |
| Oct-21-2020<br>18:52:16<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 5: Reissued: Opened             | DM1: Please update the ITEM LEVEL comment with a FORM LEVEL comment of "Not Applicable". Please review and update as appropriate. |
| Oct-21-2020<br>09:57:27<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 5: Answered                     | Form updated. Thank you.  |
| Oct-21-2020<br>09:57:00<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | <b>Data Entry</b><br>: Not Applicable | Initial Entry   |
| Oct-20-2020<br>06:21:37<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 5: Opened                       | DM: Kindly mark the form as NA as subject is discontinued already. Thank you.   |
| Sep-16-2020<br>01:18:48<br>(UTC-03:00)                         | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 4: Closed                       | Response satisfies query  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

|   |                 |                        |                           |  |
|---|-----------------|------------------------|---------------------------|--|
| City of Buenos Aires                                  |                 |                        |                           |  |
| Sep-15-2020 12:45:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | Query 4: Answered         | Changed data per query   |
| Sep-15-2020 11:43:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 4: Opened           | DM: Kindly mark the form as NA if the visit has not started yet. Thank you.  |
| Sep-15-2020 05:00:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Closed           | Response satisfies query   |
| Sep-14-2020 11:24:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered         | Answer Auto Query  |
| Sep-14-2020 11:24:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Romina Barrera (b) (4) | <b>Data Entry</b> :       | Transcription Error  |
| Sep-12-2020 04:33:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Reissued: Opened | DM2: As Visit 2 is not yet applicable, Kindly consider to remove data from this CRF and add form level comment 'Not Applicable'. |
| Sep-10-2020 11:07:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Answered         | Visit 2 is not yet applicable.   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

|   |                 |                        |                           |   |
|---|-----------------|------------------------|---------------------------|---|
| Sep-09-2020<br>11:52:35<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Reissued: Opened | DM1: Per response kindly consider removing the entry.   |
| Sep-09-2020<br>11:07:26<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Answered         | Subject COVID ill. Visit 2 not applicable.  |
| Sep-08-2020<br>01:19:10<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Reissued: Opened | DM:Per completion guidelines, 'If no sample was collected or sample was not collected according to protocol, select "No" and provide reason why sample was not collected at protocol-specified timepoint in the space provided below.'Kindly review and update. |
| Sep-07-2020<br>13:35:13<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Answered         | Transcription Error   |
| Sep-07-2020<br>13:34:53<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened           | 'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.  |
| Sep-07-2020<br>13:34:53<br>(UTC-03:00)                            | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted          | Close Auto Query  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

|   |                 |                        |   |  |
|---|-----------------|------------------------|---|--|
| City of Buenos Aires                                  |                 |                        |   |  |
| Sep-07-2020 13:34:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Data Entry<br>: NO  | Transcription Error  |
| Sep-07-2020 13:34:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-27-2020 09:28:05 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted  | Close Auto Query   |
| Aug-27-2020 09:27:56 (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-27-2020 09:27:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Data Entry<br>: YES<br>Date of Collection:<br><br>Aug/26/2020 | Initial Entry  |

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

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

|  |                 |                     |  |                     |
|--|-----------------|---------------------|--|---------------------|
| Sep-18-2020 01:21:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>                                   | Transcription Error |
| Sep-10-2020 11:07:43<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Visit 2 is not yet applicable. | Initial Entry       |

5 a

| Date   | Location        | User                | Value  | Reason                           |
|--|-----------------|---------------------|--|----------------------------------|
| Sep-07-2020 13:34:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>Sample ID: <del>BP2FFD</del> | Transcription Error<br>(DELETED) |
| Aug-27-2020 09:28:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BP2FFD            | Initial Entry                    |

5.a Sample ID

| Date   | Location                                  | User                      | Value                                   | Reason  |
|--|---|---------------------------|---|---|
| Sep-08-2020 01:27:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)          | Query 1 : Closed                        | Response satisfies query  |
| Sep-07-2020 13:34:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)          | <b>Data Entry:</b><br><del>BP2FFD</del> | Transcription Error<br>(DELETED)  |
| Sep-07-2020 13:34:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | auto query<br>(autoquery) | Query 1 : Answered                      | Transcription Error   |
| Sep-04-2020 22:22:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)      | Query 1 : Opened                        | DMW4621236;This Barcode is already recorded more than once (for the same subject). Please |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314134

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

|   |                 |                  |                                  |                                   |
|---|-----------------|------------------|----------------------------------|-----------------------------------|
|   |                 |                  |                                  | review and update as appropriate. |
| Aug-27-2020<br>09:28:05<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP2FF<br>D | Initial Entry                     |

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314134

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 20:34

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

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Formulation:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**6. Body Side:**

| Date                 | Location        | User             | Value              | Reason        |
|----------------------|-----------------|------------------|--------------------|---------------|
| Oct-04-2020 14:37:32 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314134

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 20:34

|                                  |  |                  |          |  |
|----------------------------------|--|------------------|----------|--|
| (UTC-03:00) City of Buenos Aires |  | (b) (4), (b) (6) | Not Done |  |
|----------------------------------|--|------------------|----------|--|

**7. Route:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**8. Actual Dose:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**9. Unit:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

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

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-04-2020 14:37:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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*I. Date of Visit*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-14-2020 17:17:40<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/12/2020 | 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:** 12314134**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-12-2020 17:25:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-12-2020 17:25:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Oct-12-2020 17:25:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Oct-12-2020 17:25:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-12-2020 17:25:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/12/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-12-2020 17:25:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BRXTR1 | 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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-12-2020 17:25:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BRXTR1 | Initial Entry |

**5.b**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Oct-12-2020 17:27:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BRXTRH | Initial Entry |

**5.b Sample ID**

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Oct-12-2020 17:27:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br>BRXTRH | Initial Entry |

**5.c**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Oct-12-2020 18:54:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BPT7JB | Initial Entry |

**5.c Sample ID**

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Oct-12-2020 18:54:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo<br>(b) (4) | <b>Data Entry:</b><br>BPT7JB | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/03/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - 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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Date of Visit**

| Date   | Location        | User                      | Value                            | Reason   |
|--|-----------------|---------------------------|----------------------------------|--|
| Sep-07-2020 16:09:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted                 | Close Auto Query   |
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Deleted                 | Close Auto Query   |
| Sep-07-2020 16:07:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(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.          |
| Sep-07-2020 16:07:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(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. |
| Sep-07-2020 16:07:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Sep/3/2020 | Initial Entry  |

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

| Date   | Location        | User                    | Value                         | Reason        |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Sep-07-2020 16:07:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>COVID_A | Initial Entry |

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020**Form Version:** 21-Aug-2020 02:52**Site No:** 1231**Subject No:** 12314134**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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 20:34[Back to Form](#)**1. Date of Assessment:**

| Date   | Location        | User                | Value                            | Reason   |
|--|-----------------|---------------------|----------------------------------|--|
| Oct-05-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed                  | Response satisfies query   |
| Oct-02-2020 13:58:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Answered                | CRF has been updated. Thank you.   |
| Sep-24-2020 05:31:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Reissued:Opened         | ClinQuery: CRFs can be completed and updated as needed.  |
| Sep-23-2020 17:01:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Reissued:Candidate      | ClinQuery: CRFs can be completed and updated as needed.  |
| Sep-19-2020 12:26:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered                | These CRF cannot be completed because illness is ongoing. Thank you.   |
| Sep-14-2020 16:22:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened                  | CLINQuery: If appropriate, please complete healthcare utilization and ILLNESS_DETAIL CRF as these are required CRF |
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>Sep/3/2020 | Initial Entry  |

**2. Date of First Symptom Started:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Aug/27/2020 | Initial Entry |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

3. Symptoms Ongoing?

| Date   | Location        | User             | Value   | Reason          |
|--|-----------------|------------------|---|-----------------|
| Sep-29-2020 18:39:33<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO<br>Date of Last Symptom Resolved:<br>Sep/25/2020 | New Information |
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>YES   | Initial Entry   |

4.a

| Date   | Location        | User             | Value   | Reason          |
|--|-----------------|------------------|---|-----------------|
| Sep-16-2020 13:40:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Symptoms: FEVER<br>Symptom Present: YES | New Information |
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Symptoms: FEVER<br>Symptom Present: NO  | Initial Entry   |

4.a Symptoms:

| Date   | Location        | User             | Value                       | Reason        |
|--|-----------------|------------------|-----------------------------|---------------|
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>FEVER | Initial Entry |

4.a Was symptom present?

| Date   | Location        | User             | Value                     | Reason          |
|--|-----------------|------------------|---------------------------|-----------------|
| Sep-16-2020 13:40:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>YES | New Information |
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO  | Initial Entry   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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

4.b

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms: NEW OR INCREASED COUGH<br>Symptom P present: YES | Initial Entry |

4.b Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

4.c

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms: NEW OR INCREASED SHORTNESS OF BREATH<br>Symptom Present: NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

4.c Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

4.d

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Symptoms: CHILLS<br>Symptom Present: NO | Initial Entry |

4.d Symptoms:

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>CHILLS | Initial Entry |

4.d Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

4.e

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms NEW OR INCREASE<br>: D MUSCLE PAIN<br>Symptom YES<br>Present: | Initial Entry |

4.e Symptoms:

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date   | Location        | User             | Value                     | Reason        |
|--|-----------------|------------------|---------------------------|---------------|
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

4.f

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms NEW LOSS OF TAS<br>: TE OR SMELL<br>Symptom NO<br>Present: | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12314134

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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 20:34

4.f Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW LOSS OF TASTE OR SWEET TASTE | Initial Entry |

4.f Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.g

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASED SORE THROAT<br><b>Symptom Present:</b> NO | Initial Entry |

4.g Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

**Form Version:** 21-Aug-2020 02:52

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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 20:34

**4.h**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> DIARRHEA<br><b>Symptom Present:</b> NO | Initial Entry |

**4.h Symptoms:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

**4.h Was symptom present?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.i**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-07-2020 16:08:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> VOMITING<br><b>Symptom Present:</b> NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

4.i Symptoms:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>VOMITING | Initial Entry |

4.i Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 16:08:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

5.a

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-16-2020 13:40:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Symptoms - Other: headache | Initial Entry |

5.a Symptoms - Other Text:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-16-2020 13:40:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>headache | Initial Entry |

5.b

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-22-2020 08:38:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Symptoms - Other: rhinorrhea | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:52

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.b Symptoms - Other Text:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-22-2020 08:38:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>rhinorrhea | Initial Entry |

**5.c**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-28-2020 11:24:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Symptoms - Other: ABDOMINAL PAIN | Initial Entry |

**5.c Symptoms - Other Text:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-28-2020 11:24:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ABDOMINAL PAIN | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Sep-07-2020 16:09:14<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/03/2020

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: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Actual Date of Collection:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-07-2020 16:09:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/3/2020 | Initial Entry |

**2. Specimen Type:**

| Date   | Location        | User                | Value                                  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 16:09:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SWABBED MATERIAL | Initial Entry |

**3. Specimen Collection Location:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-07-2020 16:09:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NASOPHARYNX | Initial Entry |

**4. Assay Code and Description:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Sep-07-2020 16:09:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | Initial Entry |

**5. Device Type:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Sep-07-2020 16:09:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |

**6. Trade Name:**

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Sep-07-2020 16:09:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>ATILA BIOSYSTEMS IAMP CO<br>VID-19 DETECTION KIT | Initial Entry |

**7. Test Result:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Sep-07-2020 16:09:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEGATIVE | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Sep/03/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Actual Date of Collection:**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/28/2020 | Initial Entry |

**2. Specimen Type:**

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>SWABBED MATERIAL | Initial Entry |

**3. Specimen Collection Location:**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NASOPHARYNX | Initial Entry |

**4. Assay Code and Description:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | Initial Entry |

**5. Device Type:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |

**6. Trade Name:**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Sep/03/2020**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314134**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34

|  |                 |                           |  |   |
|--|-----------------|---------------------------|--|---|
| Nov-13-2020 09:23:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed  | Close Auto Query  |
| Nov-13-2020 09:23:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>CDC 2019-NCOV REAL-TIME<br>RT-PCR DIAGNOSTIC PANEL | Transcription Error   |
| Nov-13-2020 09:22:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened  | Trade Name is Other, however Trade Name Other, Specify is not completed. Please update. |
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>OTHER  | Initial Entry   |

**7. Test Result:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>POSITIVE | Initial Entry |

**8. Comments/Findings/Details:**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Nov-12-2020 10:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Swab material collected in Htal Municipal de Trauma y Emergencias Dr. Federico Abete. Pablo Nogues. Malvinas Argentinas. Buenos Aires | Initial Entry |

**9. Trade Name Other, Specify:**

| Date   | Location        | User             | Value           | Reason                   |
|--|-----------------|------------------|-----------------|--------------------------|
| Nov-13-2020 12:45:36<br>(UTC-03:00) City of Buenos | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/03/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

|  |   |                           |                              |  |
|--|---|---------------------------|------------------------------|--|
| Aires  |   |                           |                              |  |
| Nov-13-2020<br>09:22:17<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | auto query<br>(autoquery) | Query 1:<br>Answered         | Transcription Error  |
| Nov-13-2020<br>09:22:17<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)          | <b>Data Entry:</b>           | Transcription Error  |
| Nov-13-2020<br>04:56:11<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(b) (4)   | Query 1:<br>Opened           | pcr rt is not indicated on the FDA-cleared (including Emergency Use Authorization) diagnostic list and is not indicated as 'CLIA certified lab' or 'ISO 15189 accredited lab' . Please verify and update as appropriate. Otherwise, please provide clarification.<br>(b) (4) |
| Nov-12-2020<br>10:56:09<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)          | <b>Data Entry:</b><br>PCR RT | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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 20:34

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-07-2020 16:09:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-07-2020 16:09:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB_SELF | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 16:09:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>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        |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 16:09:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>sample collected by team physician | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-07-2020 16:09:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-07-2020 16:09:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Sep-09-2020 11:51:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed  | Close Auto Query   |
| Sep-08-2020 05:03:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-07-2020 16:09:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-07-2020 16:09:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Sep/3/2020 | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-09-2020 11:51:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BP2D27 | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-09-2020 11:51:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BP2D27 | Initial Entry |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-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: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**I.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Type of Practitioner: SPECIALIST<br>Occurrence of Visits or Contacts: NO | Initial Entry |

**I.a Physician or Healthcare Professional:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SPECIALIST | Initial Entry |

**I.a Occurrence of Visits or Contacts:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**I.b**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Type of Practitioner: EMERGENCY ROOM<br>Occurrence of Visits or Contacts: YES<br>Number of Visits or Contacts: 1 | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/03/2020

Form Version: 15-Sep-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: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

***1.b Physician or Healthcare Professional:***

| Date  | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>EMERGENCY ROOM | Initial Entry |

***1.b Occurrence of Visits or Contacts:***

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br><i>Number of Visits or Contacts:</i><br><br>1 | Initial Entry |

***1.c***

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

***1.c Physician or Healthcare Professional:***

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>PRIMARY CARE PHYSICIAN | Initial Entry |

***1.c Occurrence of Visits or Contacts:***

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/03/2020

Form Version: 15-Sep-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: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

*I.d*

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> URGENT CARE<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

*I.d Physician or Healthcare Professional:*

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>URGENT CARE | Initial Entry |

*I.d Occurrence of Visits or Contacts:*

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*I.e*

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-27-2020 12:50:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> TELEPHONE CONSULTATION<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/03/2020**Form Version:** 15-Sep-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:** 12314134**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34***1.e Physician or Healthcare Professional:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>TELEPHONE CONSULTATION | Initial Entry |

***1.e Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.f***

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> OTH<br>R<br><b>Occurrence of Visits or C<br/>ontacts:</b> NO | Initial Entry |

***1.f Physician or Healthcare Professional:***

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>OTHER | Initial Entry |

***1.f Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/03/2020

**Form Version:** 15-Sep-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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

|   |                 |                     |                          |               |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-27-2020 12:50:31<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |
|---|-----------------|---------------------|--------------------------|---------------|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/03/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Category of Clinical Event:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Sep-27-2020 12:53:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>POTENTIAL COVID-19 ILLNESS | Initial Entry |

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

| Date   | Location        | User                    | Value              | Reason   |
|--|-----------------|-------------------------|--------------------|--|
| Nov-13-2020 12:56:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Rupal N Shah<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Nov-12-2020 10:59:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)        | Query 1: Answered  | Information has been updated. There's a report on 28/AUG/2020 of a positive test in the National integrated health information system. |
| Nov-12-2020 08:42:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)        | Query 1: Opened    | CLIQUEY: please clarify how COVID-19 diagnosis was made as there is no local test result reported in COVID TEST CRF.                   |
| Nov-12-2020 05:13:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Rupal N Shah<br>(b) (4) | Query 1: Candidate | CLIQUEY: please clarify how COVID-19 diagnosis was made as there is no local test result reported in COVID TEST CRF.                   |
| Sep-27-2020 12:53:59                                     | ACV0PFEINFP6000 | (b) (4), (b) (6)        | <b>Data Entry:</b> | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Sep/03/2020

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

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

|                                  |  |                  |   |  |
|----------------------------------|--|------------------|---|--|
| (UTC-03:00) City of Buenos Aires |  | (b) (4), (b) (6) | YES<br><i>Respiratory Illness Diagnosis:</i><br><br>Covid 19 disease<br><br>Date of Diagnosis:<br><br>Aug/28/2020 |  |
|----------------------------------|--|------------------|---|--|

**3. Toxicity Grade:**

| Date   | Location        | User                | Value                   | Reason              |
|--|-----------------|---------------------|-------------------------|---------------------|
| Sep-28-2020 11:29:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Transcription Error |
| Sep-27-2020 12:53:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>3 | Initial Entry       |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-02-2020 12:32:42<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History  
on Sep/03/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Date of Assessment:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-02-2020 12:32:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/13/2020 | Initial Entry |

**2. Location of Assessment:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-02-2020 12:32:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>CHEST | Initial Entry |

**3. Type of Imaging Exam:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-02-2020 12:32:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>X-RAY | Initial Entry |

**4. Assessment:**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-02-2020 12:32:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NORMAL | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/24/2020**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:** 12314134**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Date of Visit**

| Date   | Location        | User                      | Value                             | Reason   |
|--|-----------------|---------------------------|-----------------------------------|--|
| Dec-27-2020 10:08:43<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted                  | Close Auto Query   |
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Deleted                  | Close Auto Query   |
| Dec-27-2020 10:04:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(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-27-2020 10:04:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(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-27-2020 10:04:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)       | <b>Data Entry:</b><br>Dec/24/2020 | Initial Entry  |

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

| Date   | Location        | User                    | Value                         | Reason        |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Dec-27-2020 10:04:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>COVID_B | Initial Entry |

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020**Form Version:** 10-Dec-2020 02:29**Site No:** 1231**Subject No:** 12314134**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Date of Assessment:**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/24/2020 | Initial Entry |

**2. Date of First Symptom Started:**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/16/2020 | Initial Entry |

**3. Symptoms Ongoing?**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>Date of Last Symptom Resolved:<br><br>Dec/25/2020 | Initial Entry |

**4.a**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> FEVER<br><b>Symptom Present:</b> NO | Initial Entry |

**4.a Symptoms:**

| Date   | Location        | User             | Value                       | Reason        |
|--|-----------------|------------------|-----------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**4.a Was symptom present?**

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

4.b

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Symptoms: NEW OR INCREASED COUGH<br><br>Symptom Present: NO | Initial Entry |

4.b Symptoms:

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

4.c

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH<br><br>Symptom Present: NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

4.c Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.d

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms: CHILLS<br>Symptom Present: NO | Initial Entry |

4.d Symptoms:

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

4.d Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.e

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptom NEW OR INCREASED | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

|  |  |  |                   |  |
|--|--|--|-------------------|--|
|  |  |  | s: ED MUSCLE PAIN |  |
|  |  |  | Symptom YES       |  |
|  |  |  | Present:          |  |

4.e Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

4.f

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms NEW LOSS OF TASTE OR SMELL<br>Symptom NO<br>Present: | Initial Entry |

4.f Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

4.g

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptom NEW OR INCREASED SORE THROAT<br>Symptom YES<br>Present: | Initial Entry |

4.g Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

4.h

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-27-2020 10:06:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms: DIARRHEA<br>Symptom Present: NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020**Form Version:** 10-Dec-2020 02:29**Site No:** 1231**Subject No:** 12314134**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34**4.h Symptoms:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

**4.h Was symptom present?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.i**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> VOMITING<br><b>Symptom Present:</b> NO | Initial Entry |

**4.i Symptoms:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**4.i Was symptom present?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:06:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.a**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-27-2020 10:07:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms - Other:</b> Headache | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.a Symptoms - Other Text:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-27-2020 10:07:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Headache | Initial Entry |

**5.b**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-27-2020 10:07:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms - Other:</b> Asthenia | Initial Entry |

**5.b Symptoms - Other Text:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-27-2020 10:07:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Asthenia | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Dec/24/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Dec-27-2020 10:07:59<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/24/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Actual Date of Collection:**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-27-2020 10:07:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/24/2020 | Initial Entry |

**2. Specimen Type:**

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:07:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>SWABBED MATERIAL | Initial Entry |

**3. Specimen Collection Location:**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-27-2020 10:07:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NASOPHARYNX | Initial Entry |

**4. Assay Code and Description:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-27-2020 10:07:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | Initial Entry |

**5. Device Type:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-27-2020 10:07:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |

**6. Trade Name:**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:07:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>ATILA BIOSYSTEMS IAMP CO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/24/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

|              |  |  |                      |  |
|--------------|--|--|----------------------|--|
| Buenos Aires |  |  | VID-19 DETECTION KIT |  |
|--------------|--|--|----------------------|--|

**7. Test Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-27-2020 10:07:59<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <u>Data Entry:</u><br>NEGATIVE | Initial Entry |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-27-2020 10:08:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Dec-27-2020 10:08:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB_SELF | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-27-2020 10:08:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>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-27-2020 10:08:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Sample collected by a team physician | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314134**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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 20:34[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-27-2020 10:08:43<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Dec-27-2020 10:08:43<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Dec-28-2020 11:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Dec-27-2020 10:08:43<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Dec-27-2020 10:08:43<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Dec/24/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-28-2020 11:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPW8DL | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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 20:34

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-28-2020 11:56:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPW8DL | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/24/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-27-2020 10:09:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Type of Practitioner: SPECIALIST<br>Occurrence of Visits or Contacts: NO | Initial Entry |

**1.a Physician or Healthcare Professional:**

| Date  | Location        | User             | Value                            | Reason        |
|---|-----------------|------------------|----------------------------------|---------------|
| Dec-27-2020 10:09:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>SPECIALIST | Initial Entry |

**1.a Occurrence of Visits or Contacts:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:09:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**1.b**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-27-2020 10:09:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Type of Practitioner: EMERGENCY ROOM<br>Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/24/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

***1.b Physician or Healthcare Professional:***

| Date   | Location        | User             | Value                                | Reason        |
|--|-----------------|------------------|--------------------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>EMERGENCY ROOM | Initial Entry |

***1.b Occurrence of Visits or Contacts:***

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.c***

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Type of Practitioner: PRIMARY CARE PHYSICIAN<br>Occurrence of Visits or Contacts: NO | Initial Entry |

***1.c Physician or Healthcare Professional:***

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>PRIMARY CARE PHYSICIAN | Initial Entry |

***1.c Occurrence of Visits or Contacts:***

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.d***

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/24/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> URGENT CARE<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

*1.d Physician or Healthcare Professional:*

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>URGENT CARE | Initial Entry |

*1.d Occurrence of Visits or Contacts:*

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*1.e*

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> TELEPHONE CONSULTATION<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/24/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314134**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34***1.e Physician or Healthcare Professional:***

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>TELEPHONE CONSULTATION | Initial Entry |

***1.e Occurrence of Visits or Contacts:***

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.f***

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> OTH<br>R<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

***1.f Physician or Healthcare Professional:***

| Date   | Location        | User             | Value                       | Reason        |
|--|-----------------|------------------|-----------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>OTHER | Initial Entry |

***1.f Occurrence of Visits or Contacts:***

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

|   |                 |                     |                          |               |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-27-2020 10:09:39<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |
|---|-----------------|---------------------|--------------------------|---------------|



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Category of Clinical Event:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-27-2020 10:10:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>POTENTIAL COVID-19 ILLNESS | Initial Entry |

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

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-27-2020 10:10:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES<br><i>Respiratory Illness Diagnosis:</i><br><br>Upper airway catarrh<br><br>Date of Diagnosis:<br><br>Dec/26/2020 | Initial Entry |

**3. Toxicity Grade:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Dec-27-2020 10:10:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>1 | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/06/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Date of Visit**

| Date  | Location        | User                | Value                            | Reason        |
|---|-----------------|---------------------|----------------------------------|---------------|
| Oct-08-2020 11:21:03<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Oct/6/2020 | Initial Entry |

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

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-08-2020 11:21:03<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>COVID_A1 | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/06/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314134**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
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 20:34[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-08-2020 11:21:20<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-08-2020 11:21:20<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value  | Reason  |
|---|-----------------|---------------------------|--|---|
| Oct-08-2020 12:33:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query  |
| Oct-08-2020 11:21:20<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Oct-08-2020 11:21:20<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/6/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                         | Value  | Reason        |
|---|-----------------|------------------------------|--|---------------|
| Oct-08-2020 12:33:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Romina<br>Barrera<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BP1VPG | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/06/2020

**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.a Sample ID**

| Date  | Location        | User                         | Value                        | Reason        |
|---|-----------------|------------------------------|------------------------------|---------------|
| Oct-08-2020 12:33:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Romina<br>Barrera<br>(b) (4) | <b>Data Entry:</b><br>BP1VPG | Initial Entry |

**5.b**

| Date  | Location        | User                         | Value  | Reason        |
|---|-----------------|------------------------------|--|---------------|
| Oct-08-2020 12:34:07<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Romina<br>Barrera<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BNV5ZC | Initial Entry |

**5.b Sample ID**

| Date  | Location        | User                         | Value                        | Reason        |
|---|-----------------|------------------------------|------------------------------|---------------|
| Oct-08-2020 12:34:07<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Romina<br>Barrera<br>(b) (4) | <b>Data Entry:</b><br>BNV5ZC | Initial Entry |

**5.c**

| Date  | Location        | User                         | Value  | Reason        |
|---|-----------------|------------------------------|--|---------------|
| Oct-08-2020 12:35:40<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Romina<br>Barrera<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BNV5ZS | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                         | Value                        | Reason        |
|---|-----------------|------------------------------|------------------------------|---------------|
| Oct-08-2020 12:35:40<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Romina<br>Barrera<br>(b) (4) | <b>Data Entry:</b><br>BNV5ZS | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled Visit on Jan/28/2021

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - 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 20:34

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**1. Date of Visit**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Jan-28-2021 12:12:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Jan/28/2021 | Initial Entry |

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

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Jan-28-2021 12:12:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>COVID_B1 | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/28/2021

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
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 20:34

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-28-2021 12:12:45<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-28-2021 12:12:45<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value   | Reason  |
|---|-----------------|---------------------------|---|---|
| Jan-29-2021 09:25:32<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed   | Close Auto Query  |
| Jan-29-2021 05:15:15<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)       | Query 1: Opened   | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Jan-28-2021 12:12:45<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Jan-28-2021 12:12:45<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/28/2021 | Initial Entry   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/28/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314134

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
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 20:34

5.a

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Jan-29-2021 09:25:32<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <u>Data Entry:</u><br>Sample ID: BRYWL5 | Initial Entry |

5.a Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-29-2021 09:25:32<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <u>Data Entry:</u><br>BRYWL5 | Initial Entry |

5.b

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Jan-29-2021 09:25:41<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <u>Data Entry:</u><br>Sample ID: BRYWL6 | Initial Entry |

5.b Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-29-2021 09:25:41<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <u>Data Entry:</u><br>BRYWL6 | Initial Entry |

5.c

| Date  | Location        | User                   | Value                                   | Reason        |
|---|-----------------|------------------------|---|---------------|
| Jan-29-2021 12:52:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6) | <u>Data Entry:</u><br>Sample ID: BPWFGX | Initial Entry |

5.c Sample ID

| Date  | Location        | User                   | Value                        | Reason        |
|---|-----------------|------------------------|------------------------------|---------------|
| Jan-29-2021 12:52:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6) | <u>Data Entry:</u><br>BPWFGX | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/28/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
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**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:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.d**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Jan-29-2021 13:34:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID:</b> BRYWHC | Initial Entry |

**5.d Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-29-2021 13:34:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BRYWHC | Initial Entry |



Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12314134

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - 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 20:34

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

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-18-2020 01:21:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sep/14/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-18-2020 01:21:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 01:21:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO LONGER MEETS ELIGIBILITY CRITERIA | Initial Entry |

**4. Specify Status:**

| Date   | Location                                  | User                    | Value                | Reason   |
|--|---|-------------------------|----------------------|--|
| Nov-10-2020 18:55:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)        | Query 1:<br>Closed   | Response satisfies query   |
| Nov-10-2020 08:56:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)     | Query 1:<br>Answered | The subject had a probable Covid illness diagnosis on 28 AUG 2020. Thank you |
| Nov-10-2020 06:23:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(b) (4) | Query 1:<br>Opened   | Please review Specify Status field, the following text                       |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** DISPOSITION - TREATMENT - 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 20:34

|  |                 |                  |  |  |
|--|-----------------|------------------|--|--|
| Aires  |                 |                  |  | was indicated in the comment field [Previous clinical or microbiological diagnosis of COVID-19]. Any other key data should be collected on the appropriate page. Please review and update as necessary.<br>(b) (4) |
| Sep-18-2020<br>01:21:37<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Previous clinical or microbiological diagnosis of COVID-19 | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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*I. Date of Visit*

| Date  | Location        | User                          | Value                             | Reason        |
|---|-----------------|-------------------------------|-----------------------------------|---------------|
| Mar-20-2021 10:28:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Martina<br>Davalli<br>(b) (4) | <b>Data Entry:</b><br>Mar/19/2021 | Initial Entry |

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314134

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

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

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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

| Date  | Location        | User                          | Value   | Reason  |
|---|-----------------|-------------------------------|---|---|
| Mar-20-2021 10:29:23<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Deleted  | Close Auto Query  |
| Mar-20-2021 10:28:58<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Candidate  | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Mar-20-2021 10:28:58<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Martina<br>Davalli<br>(b) (4) | <b>Data Entry:</b><br>Participant is willing to return fo<br>r Vaccination 3<br>Participant is:<br><br>eligible per other protocol all<br>owance(s) and confirmed to h<br>ave received only placebo at<br>Vaccination 1/2 | Initial Entry   |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** DATE OF VISIT - 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 20:34

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*I. Date of Visit*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Mar-23-2021 16:50:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/23/2021 | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1231

**Subject No:** 12314134

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION - 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 20:34

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***1. Consent Was:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Mar-23-2021 16:52:43<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Mar/23/2021 | 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, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Mar-23-2021 16:53:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/23/2021 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                                    | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Mar-23-2021 16:53:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>REPEAT SCREENING 1 | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Mar-23-2021 16:53:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/23/2021 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

**6.a**

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

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



Header Text: C4591001

Visit: V101\_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

|  |                 |                         |   |               |
|--|-----------------|-------------------------|---|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin in Beta_PX113<br><b>Result::</b> NEGATIVE<br><b>Not Done::</b> | Initial Entry |
|--|-----------------|-------------------------|---|---------------|

6.a Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

6.a Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Mar-23-2021 16:54:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEGATIVE | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-23-2021 16:55:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Mar-23-2021 16:55:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Mar-26-2021 11:39:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed   | Close Auto Query   |
| Mar-26-2021 08:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-23-2021 16:55:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-23-2021 16:55:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Mar/23/2021 | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

5.a

| Date  | Location        | User                             | Value  | Reason        |
|---|-----------------|----------------------------------|--|---------------|
| Mar-26-2021 11:39:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID: BS1R5C</b> | Initial Entry |

5.a Sample ID

| Date  | Location        | User                             | Value                        | Reason        |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Mar-26-2021 11:39:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br>BS1R5C | Initial Entry |

5.b

| Date  | Location        | User                             | Value  | Reason        |
|---|-----------------|----------------------------------|--|---------------|
| Mar-26-2021 11:52:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID: BS1PZJ</b> | Initial Entry |

5.b Sample ID

| Date  | Location        | User                             | Value                        | Reason        |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Mar-26-2021 11:52:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br>BS1PZJ | Initial Entry |

5.c

| Date  | Location        | User                             | Value  | Reason        |
|---|-----------------|----------------------------------|--|---------------|
| Mar-26-2021 12:05:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID: BP1X4W</b> | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

*5.c Sample ID*

| Date  | Location        | User                                   | Value                        | Reason        |
|---|-----------------|--|------------------------------|---------------|
| Mar-26-2021 12:05:00<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Agustin<br>Morato<br>Cabral<br>(b) (4) | <b>Data Entry:</b><br>BP1X4W | 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, Frozen, Verified

Site No: 1231

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

Subject No: 12314134

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-23-2021 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Mar-23-2021 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Mar-26-2021 10:19:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed   | Close Auto Query   |
| Mar-26-2021 08:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-23-2021 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-23-2021 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Mar/23/2021 | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.a**

| Date   | Location        | User                             | Value  | Reason        |
|--|-----------------|----------------------------------|--|---------------|
| Mar-26-2021 10:19:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br><b>Sample ID:</b> BRN0V1 | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                             | Value                        | Reason        |
|--|-----------------|----------------------------------|------------------------------|---------------|
| Mar-26-2021 10:19:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Agustin Morato Cabral<br>(b) (4) | <b>Data Entry:</b><br>BRN0V1 | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314134

Generated By: (b) (4)

Form: VACCINATION - 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 20:34

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                          | Reason        |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/23/2021 11:11 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date                 | Location        | User             | Value              | Reason        |
|----------------------|-----------------|------------------|--------------------|---------------|
| Mar-23-2021 16:56:27 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314134

Generated By: (b) (4)

Form: VACCINATION - 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 20:34

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

7. Route:

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30.0 | Initial Entry |

9. Unit:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30 MINUTES | Initial Entry |

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

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Mar-23-2021 16:56:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

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

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

Header Text: C4591001

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Site No: 1231

Subject No: 12314134

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

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**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                           | Value                   | Reason  |
|--|-----------------|--------------------------------|-------------------------|---|
| Jan-19-2021 16:38:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)               | Query 1: Closed         | event is the AE number only   |
| Jan-19-2021 15:08:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti<br>(b) (4) | Query 1: Answered       | Changed data per query  |
| Jan-18-2021 16:32:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)               | Query 1: Opened         | Clinical As per CRF CG 8.50.2.5, the toxicity grade for "Exposure During Pregnancy" is reported as Not Applicable |
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc)        | <b>Data Entry:</b><br>1 | Initial Entry   |

**3. Adverse Event:**

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

| Date   | Location        | User                | Value             | Reason   |
|--|-----------------|---------------------|-------------------|--|
| Mar-13-2021 22:20:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 2: Closed   | Response satisfies query   |
| Mar-13-2021 11:59:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 2: Answered | SAE form was sent because the volunteer was hospitalized from Feb 12, 2021 to Feb 13, 2021 for |

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1231

**Subject No:** 12314134

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

|  |                 |                     |  |  |
|--|-----------------|---------------------|--|--|
|  |                 |                     |  | incomplete abortion and a uterine evacuator curettage was performed.   |
| Mar-11-2021 12:50:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 2: Opened                              | Clinical - please remove the serious adverse event for elective abortion; all info on misoprostil / D & C go on PG Safety report for an elective termination   |
| Mar-11-2021 12:50:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed                              | rewording  |
| Mar-11-2021 12:44:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Reissued:Opened                     | Clinical - please remove the serious adverse event for elective abortion   |
| Mar-10-2021 12:53:30<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Answered                            | The information regarding the end date has already been updated  |
| Mar-10-2021 12:48:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened                              | Clinical - A SAE report (#2021259645) was submitted for 'Induced Abortion'. As this is an elective procedure, not a complication of PG, no new event is required. Please enter end date on Drug Exposed PG event/send PG safety update (#2021024046) |
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Drug Exposed Pregnancy | Initial Entry  |

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4. Start Date Time:

| Date   | Location        | User                        | Value                                  | Reason        |
|--|-----------------|-----------------------------|--|---------------|
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(4),<br>(b) (6) | <u>Data Entry:</u><br>Dec/7/2020 08:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date   | Location        | User                | Value   | Reason          |
|--|-----------------|---------------------|---|-----------------|
| Mar-10-2021 12:52:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>NO<br>End Date Time:<br>Feb/13/2021 UNK:UNK | New Information |
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>YES   | Initial Entry   |

6. Toxicity Grade:

| Date   | Location        | User                           | Value                                | Reason              |
|--|-----------------|--------------------------------|--------------------------------------|---------------------|
| Jan-19-2021 15:08:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti<br>(b) (4) | <u>Data Entry:</u><br>Not Applicable | Initial Entry       |
| Jan-19-2021 15:08:21<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti<br>(b) (4) | <u>Data Entry:</u>                   | Transcription Error |
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)            | <u>Data Entry:</u><br>1              | 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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

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|  |                 |                           |  |   |
|--|-----------------|---------------------------|--|---|
| Mar-14-2021 05:03:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Closed  | Response satisfies query  |
| Mar-13-2021 11:56:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Answered  | New Information   |
| Mar-13-2021 11:56:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>NO   | New Information   |
| Mar-12-2021 08:41:05<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Opened  | SAE RECON: Drug exposed pregnancy was recorded as serious in AE CRF, however per CRF CG, seriousness criteria is met if there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly |
| Mar-12-2021 08:37:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Deleted   | Query can be addressed internally   |
| Mar-10-2021 12:54:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | For AE Drug Exposed Pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.  |
| Mar-10-2021 12:54:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Is this serious event associated with congenital anomaly or birth defect?<br><br>NO | Transcription Error   |

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

|   |                 |                  |  |               |
|---|-----------------|------------------|--|---------------|
|   |                 |                  | Did this serious event result in death?<br><br>NO<br><br>Did this serious event require or prolong hospitalization?<br><br>NO<br><br>Did this serious event result in persistent or significant disability /incapacity?<br><br>NO<br><br>Is this serious event life threatening?<br><br>NO<br><br>Other medically important serious event<br><br>YES |               |
| Jan-13-2021 10:24:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO   | Initial Entry |

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

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-13-2021 10:24:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Jan-13-2021 10:24:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s), this event is due to: | Initial Entry |

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Subject No: 12314134

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

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

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-13-2021 10:24:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

| Date   | Location        | User                           | Value                                    | Reason   |
|--|-----------------|--------------------------------|--|--|
| Mar-10-2021 12:51:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)               | <b>Data Entry:</b><br>RECOVERED/RESOLVED | New Information  |
| Jan-15-2021 09:46:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)            | Query 1: Closed                          | Close per query response   |
| Jan-13-2021 17:58:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Santiago Corradetti<br>(b) (4) | Query 1: Answered                        | As per CRF CR (Section 8.50.2.5), as long as pregnancy is still ongoing, outcome |

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

|   |                 |                        |                            |   |
|---|-----------------|------------------------|----------------------------|---|
|   |                 |                        |                            | must be 'unknown'. Thank you.   |
| Jan-13-2021 10:24:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened            | For AE Drug Exposed Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes". |
| Jan-13-2021 10:24:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | <b>Data Entry:</b> UNKNOWN | Initial Entry   |

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

| Date  | Location        | User             | Value                 | Reason        |
|---|-----------------|------------------|-----------------------|---------------|
| Jan-13-2021 10:24:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> NO | Initial Entry |

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Generated By: (b) (4)

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1. Category:

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

3. Adverse Event:

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

| Date  | Location        | User                | Value                          | Reason   |
|---|-----------------|---------------------|--------------------------------|--|
| Mar-18-2021<br>09:43:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 2: Closed                | Response satisfies query   |
| Mar-17-2021<br>11:47:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 2: Answered              | On 15MAR FU was sent with this information.  |
| Mar-16-2021<br>16:50:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 2: Opened                | Clinical - Thank you; however, SAE update (15Mar21) still has the event term 'Induced Abortion' rather than 'Incomplete Abortion'; please submit an update |
| Mar-16-2021<br>11:21:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed                | error- report not yet received   |
| Mar-16-2021<br>11:19:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Reissued:Open<br>ened | Clinical - Thank you; however, SAE update (15Mar21) still has the event term 'Induced Abortion' rather than 'Incomplete Abortion'; please                  |

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1231

**Subject No:** 12314134

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

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

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

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

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|  |                 |                           |   |   |
|--|-----------------|---------------------------|---|---|
|  |                 |                           |   | submit an update  |
| Mar-16-2021<br>10:52:42<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Answered                         | SAE form was sent on 15MAR<br>with this information.  |
| Mar-16-2021<br>02:56:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Reissued:Op<br>ened              | SAE RECON: Please confirm if a<br>follow up SAE form was sent to<br>update term in Safety database  |
| Mar-15-2021<br>16:34:38<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered                         | New Information   |
| Mar-15-2021<br>16:34:38<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)       | <b>Data Entry:</b><br>incomplete abortion | New Information   |
| Mar-13-2021<br>22:19:51<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Reissued:Op<br>ened              | Clinical - Please update the event<br>term to Incomplete Abortion in AE<br>and PG Safety report. Thank you<br>for clarifying. The induction is<br>treatment of the Incomplete<br>spontaneous Abortion           |
| Mar-13-2021<br>11:51:47<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)       | Query 1: Answered                         | The volunatry went to the guard on<br>02/12/21 for abdominal pain and<br>moderate vaginal bleeding.<br>Incomplete abortion was diagnosed<br>and she was admitted from<br>02/12/21 to 02/13/21                   |
| Mar-12-2021<br>08:43:47<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened                           | SAE<br>RECON:AER#2021259645, elective<br>abortion is not considered a<br>complication of PG, therefore per<br>CRF CG this is not considered<br>SAE. Please confirm if event<br>should be inactivated in AE CRF. |
| Mar-10-2021<br>12:50:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)       | <b>Data Entry:</b><br>Induced abortion    | Initial Entry   |

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Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314134

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

4. Start Date Time:

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Feb/11/2021 09:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date   | Location        | User                | Value   | Reason   |
|--|-----------------|---------------------|---|--|
| Mar-16-2021 11:09:10<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed   | Response satisfies query   |
| Mar-15-2021 13:47:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered   | In FU sent 09MAR, date of outcome of pregnancy 13FEB was stated. State of Subject: recovered   |
| Mar-13-2021 22:28:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened   | Clinical - End date is 13Feb21; however, PG safety report has no end date. Please review, harmonize reporting, and update where applicable |
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Feb/13/2021 19:00 | Initial Entry  |

6. Toxicity Grade:

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

7. Is the adverse event serious?

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

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314134

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Subject Initials: ---

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If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Mar-16-2021 16:49:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Closed  | Response satisfies query   |
| Mar-15-2021 13:45:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Answered  | In the FU sent on 09MAR, hospitalization and important medical event were marked   |
| Mar-13-2021 22:29:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Opened  | Clinical - Serious criteria are HOSP and Important; however, SAE report has serious criteria HOSP. Please review, harmonize reporting, and update where applicable |
| Mar-11-2021 02:34:54<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | For AE Induced abortion: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.   |
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Is this serious event associated with congenital anomaly or birth defect?<br><br>NO | Initial Entry  |

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**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314134**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

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

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

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-10-2021 12:50:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Mar-10-2021 12:50:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br><br>OTHER | Initial Entry |

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Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

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

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

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

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

| Date   | Location        | User                | Value                                    | Reason        |
|--|-----------------|---------------------|--|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Mar-10-2021 12:50:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

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

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

|   |                 |                     |                                  |                       |
|---|-----------------|---------------------|----------------------------------|-----------------------|
| Mar-14-2021 05:01:57<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>2021024046 | Updated AER in<br>SDB |
| Mar-11-2021 02:34:54<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>2021259645 | Initial Entry         |



**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

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**1. Date Treatment Unblinded :**

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Mar-20-2021 10:29:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Martina Davalli<br>(b) (4) | <b>Data Entry:</b><br>Mar/19/2021 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date   | Location        | User                       | Value   | Reason        |
|--|-----------------|----------------------------|---|---------------|
| Mar-20-2021 10:29:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Martina Davalli<br>(b) (4) | <b>Data Entry:</b><br>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

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Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314134

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 20:34

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**I. Subject Status**

| Date   | Location        | User                    | Value                                     | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Sep-18-2020 01:21:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DISCONTINUED        | Initial Entry |
| Aug-26-2020 13:13:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Aug-26-2020 13:12:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry |

**2. Subject Status Date**

| Date   | Location        | User                    | Value                             | Reason   |
|--|-----------------|-------------------------|-----------------------------------|--|
| Mar-11-2021 02:36:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Closed                   | Response satisfies query   |
| Mar-10-2021 16:42:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Answered                 | The adverse event has already been edited, it corresponds to an SAE  |
| Mar-10-2021 09:49:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Opened                   | SAE RECON:AER#2021259645 induced abortion(onset date:11Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Sep-18-2020 01:21:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sep/14/2020 | Initial Entry  |
| Aug-26-2020 13:13:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Aug/26/2020 | Initial Entry  |

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314134

**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 20:34

|   |                 |                         |                                   |               |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Aug-26-2020 13:12:00<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Aug/26/2020 | Initial Entry |
|---|-----------------|-------------------------|-----------------------------------|---------------|

090177e196ae2eb1\Final\Final On: 01-Apr-2021 03:21 (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, Verified

**Site No:** 1231

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

**Subject No:** 12314134

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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*I. Casebook Signature*

| Date  | Location        | User             | Value                                      | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-23-2020 17:06:50<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |