

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[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                        | 08 SEP 2020     |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Oct/15/2020 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [12412191]                                     |
| 2. | Birth Date:                     | (b) (6) 1955                                   |
| 3. | Sex:                            | MALE   |
| 4. | Ethnicity:                      | NOT 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:** 1241

**Subject No:** 12412191

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

**Form:** DATE OF VISIT

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Oct/15/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Oct/15/2020 |
| 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:** 1241

**Subject No:** 12412191

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Medical History Details**

|     |  |                                  |
|-----|--|----------------------------------|
| 1.a | Line/MH Number:  | [1]                              |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hemorrhoidal disease]           |
|     | Start Date:  | UNK/UNK/1980                     |
|     | Ongoing:   | YES                              |
| 1.b | Line/MH Number:  | [2]                              |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Allergic rhinitis]              |
|     | Start Date:  | UNK/UNK/2005                     |
|     | Ongoing:   | YES                              |
| 1.c | Line/MH Number:  | [3]                              |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Chronic tension headache]       |
|     | Start Date:  | UNK/UNK/1970                     |
|     | Ongoing:   | YES                              |
| 1.d | Line/MH Number:  | [4]                              |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Systemic arterial hypertension] |
|     | Start Date:  | UNK/UNK/2005                     |
|     | Ongoing:   | YES                              |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |                                   |
|-----|--|-----------------------------------|
| 1.e | Line/MH Number:  | [5]                               |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [dyslipidemia]                    |
|     | Start Date:  | UNK/UNK/2015                      |
|     | Ongoing:   | YES                               |
| 1.f | Line/MH Number:  | [6]                               |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [carotid atherosclerotic disease] |
|     | Start Date:  | UNK/UNK/2015                      |
|     | Ongoing:   | YES                               |
| 1.g | Line/MH Number:  | [7]                               |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [gastroesophageal reflux disease] |
|     | Start Date:  | UNK/UNK/2000                      |
|     | Ongoing:   | YES                               |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** HIV STATUS

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**HIV Status**

|    |  |   |
|----|--|---|
| 1. | Select appropriate response -<br>What is the subject HIV status? | The subject is NOT known to be HIV POSITIVE |
|----|--|---|

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Oct/15/2020 |
| 2. | Weight:          | [78.5]      |
| 3. | Unit:            | kg          |
| 4. | Height:          | [165.0]     |
| 5. | Unit:            | cm          |
| 6. | Body Mass Index: | [28.8]      |

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 7.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.4]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form:** RANDOMIZATION

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Oct/15/2020 |
| 2. | Randomization Number: | [269363]    |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[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/15/2020 |
| 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 | [BPTSPW] |
| 5.b | Sample ID | [BMM6T7] |
| 5.c | Sample ID | [BMM6T8] |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[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>Oct/15/2020 |
| 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 | [BRD41X] |
|-----|-----------|----------|

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** VACCINATION

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[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:   | Oct/15/2020 08:54                         |
| 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                                       |

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** DATE OF VISIT

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |            |
|----|-------|------------|
| 1. | Date: | Nov/6/2020 |
|----|-------|------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.4]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

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

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[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>Nov/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 | [BR5TY4] |
|-----|-----------|----------|

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** VACCINATION

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[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:   | Nov/6/2020 09:22                          |
| 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                                       |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Dec/4/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | SERUM                                    |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Dec/4/2020 |
| 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 | [BR7CBM] |
| 5.b | Sample ID | [BS2KH1] |
| 5.c | Sample ID | [BS2KH2] |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Signs and Symptoms**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date of Assessment:            | Nov/12/2020   |
| 2. | Date of First Symptom Started: | Nov/9/2020  |
| 3. | Symptoms Ongoing?              | NO<br>Date of Last Symptom Resolved:<br>Nov/10/2020 |

**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? | NO                                   |
| 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                                   |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |                      |          |
|-----|----------------------|----------|
| 4.i | Symptoms:            | VOMITING |
|     | Was symptom present? | YES      |

**Symptoms - Other**

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

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

|     |                        |                            |
|-----|------------------------|----------------------------|
| 5.c | Symptoms - Other Text: | [Transient global amnesia] |
|-----|------------------------|----------------------------|

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Date of Collection | Specimen Type    | Specimen Collection Location | Assay Code and Description                      | Device Type                | Form Instance                   |
|----|--------------------|------------------|------------------------------|---|----------------------------|---------------------------------|
| 1. | Nov/10/2020        | SWABBED MATERIAL | NASOPHARYNX                  | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | <a href="#">Repeating Pages</a> |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Microbiology Specimen**

|    |                               |  |
|----|-------------------------------|--|
| 1. | Actual Date of Collection:    | Nov/10/2020                              |
| 2. | Specimen Type:                | SWABBED MATERIAL                         |
| 3. | Specimen Collection Location: | NASOPHARYNX                              |
| 4. | Assay Code and Description:   | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 |
| 5. | Device Type:                  | SARS-COV-2 DIAGNOSTIC TEST               |
| 6. | Trade Name:                   | OTHER                                    |
| 7. | Test Result:                  | NEGATIVE                                 |
| 8. | Comments/Findings/Details:    | [ ]                                      |
| 9. | Trade Name Other, Specify:    | [NALT unknown]                           |



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[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: | [Subject used site swab] |

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[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>Nov/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 | [BR6696] |
|-----|-----------|----------|

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Not Complete**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[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**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Not Complete

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Health Care Utilization**

|    |  |   |
|----|--|---|
| 3. | Has the subject been hospitalized due to potential COVID-19 illness? | YES<br>Has the subject been in intensive care due to potential COVID-19 illness?<br>YES |
|----|--|---|

**Header Text:** c4591001

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

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Hospitalization Category | Hospitalization Term | Admission Date | Ongoing                                  | Form Instance                   |
|----|--------------------------|----------------------|----------------|--|---------------------------------|
| 1. | HOSPITALIZATION STATUS   | HOSPITAL             | Nov/9/2020     | NO<br>Discharge Date<br>:<br>Nov/12/2020 | <a href="#">Repeating Pages</a> |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HOSPITALIZATION DETAILS

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

**Form Status:** Data Complete, Queries

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Hospitalization Details**

|    |                           |                                      |
|----|---------------------------|--------------------------------------|
| 1. | Hospitalization Category: | HOSPITALIZATION STATUS               |
| 2. | Hospitalization Term:     | HOSPITAL                             |
| 3. | Admission Date:           | Nov/9/2020                           |
| 4. | Ongoing?                  | NO<br>Discharge Date:<br>Nov/12/2020 |

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | 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 on Nov/12/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**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 on Nov/12/2020

**Form:** ILLNESS DETAILS

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[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? | NO                         |
| 3. | Toxicity Grade:  | 3                          |

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Illness Details**

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

**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | 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 on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**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 |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Category for Lab Test | Vendor Name (DERIVED) | 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 on Nov/12/2020

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

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**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 |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**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:** 10-Oct-2020 16:04

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Date Time of Assessment | Arterial Blood Gases PaO <sub>2</sub> | FiO <sub>2</sub> (Fraction of Inhaled Oxygen) | Form Instance                   |
|----|-------------------------|---------------------------------------|---|---------------------------------|
| 1. |                         |                                       |   | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | 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 on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | 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 1 - Unscheduled

**Form:** IMAGING

Visit on Nov/12/2020

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**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 Jan/13/2021

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/13/2021 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/13/2021

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[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/13/2021 |
| 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 | [BPTKMF] |
| 5.b | Sample ID | [BRT721] |
| 5.c | Sample ID | [BRT722] |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB  
Unscheduled Visit

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| #  | Category      | AE Identifier | Adverse Event               | Start Date         | Is the Adverse Event Still Ongoing              | Form Instance                   |
|----|---------------|---------------|-----------------------------|--------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1             | Disorientation to clarify   | Nov/9/2020 UNK:UNK | NO<br>End Date Time:<br><br>Nov/12/2020 UNK:UNK | <a href="#">Repeating Pages</a> |
| 2. | ADVERSE EVENT | 2             | Vomiting                    | Nov/9/2020 UNK:UNK | NO<br>End Date Time:<br><br>Nov/10/2020 UNK:UNK | <a href="#">Repeating Pages</a> |
| 3. | ADVERSE EVENT | 3             | Dizziness                   | Nov/9/2020 UNK:UNK | NO<br>End Date Time:<br><br>Nov/10/2020 UNK:UNK | <a href="#">Repeating Pages</a> |
| 4. | ADVERSE EVENT | 4             | Transitional global amnesia | Nov/9/2020 UNK:UNK | NO<br>End Date Time:<br><br>Nov/11/2020 UNK:UNK | <a href="#">Repeating Pages</a> |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

[eCRF Audit Trail History](#)

[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)  | [Disorientation to clarify]   |
| 4. | Start Date Time:  | Nov/9/2020 UNK:UNK  |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/12/2020 UNK:UNK   |
| 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>NO |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |   |   |
|-----|---|---|
| 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>[to clarify] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |
| 11. | Was a Concomitant Medication given?   | YES   |
| 12. | Was a Non-Drug Treatment given?   | NO  |
| 13. | What was the outcome of this adverse event?:  | RECOVERED/RESOLVED  |
| 14. | Did the adverse event cause the subject to be discontinued from the study?  | NO  |
| 15. | Serious Adverse Event Number:<br>For Pfizer Use Only  | [2020449336]  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1241**Subject No:** 12412191**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Queries**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

|    |   |   |
|----|---|---|
| 1. | Category:   | ADVERSE EVENT                               |
| 2. | AE ID:  | [2]   |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Vomiting]                                  |
| 4. | Start Date Time:  | Nov/9/2020 UNK:UNK                          |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/10/2020 UNK:UNK |
| 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). | 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  |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Queries

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |  |
|-----|--|--|
| 9.  | Is this event related to study treatment:                                  | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[Unknown] |
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE   |
| 11. | Was a Concomitant Medication given?  | YES  |
| 12. | Was a Non-Drug Treatment given?  | NO   |
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED   |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO   |
| 15. | Serious Adverse Event Number:<br>For Pfizer Use Only                       | [ ]  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1241**Subject No:** 12412191**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

|    |   |   |
|----|---|---|
| 1. | Category:   | ADVERSE EVENT                               |
| 2. | AE ID:  | [3]   |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Dizziness]                                 |
| 4. | Start Date Time:  | Nov/9/2020 UNK:UNK                          |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/10/2020 UNK:UNK |
| 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). | 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  |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |  |
|-----|--|--|
| 9.  | Is this event related to study treatment:                                  | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[Unknown] |
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE   |
| 11. | Was a Concomitant Medication given?  | YES  |
| 12. | Was a Non-Drug Treatment given?  | NO   |
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED   |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO   |
| 15. | Serious Adverse Event Number:<br>For Pfizer Use Only                       | [ ]  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Adverse Event Report**

|    |   |   |
|----|---|---|
| 1. | Category:   | ADVERSE EVENT                               |
| 2. | AE ID:  | [4]   |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Transitional global amnesia]               |
| 4. | Start Date Time:  | Nov/9/2020 UNK:UNK                          |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/11/2020 UNK:UNK |
| 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). | 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  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |  |
|-----|--|--|
| 9.  | Is this event related to study treatment:                                  | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[Unknown] |
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE   |
| 11. | Was a Concomitant Medication given?  | YES  |
| 12. | Was a Non-Drug Treatment given?  | NO   |
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED   |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO   |
| 15. | Serious Adverse Event Number:<br>For Pfizer Use Only                       | [ ]  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Medication Error**

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



**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

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

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | 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:** 1241

**Subject No:** 12412191

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

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



**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Unplanned Assessments**

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

**Header Text:** c4591001

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

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

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled **Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16 **Form Status:** Not Started

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled **Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26 **Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**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? |     |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (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:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241    **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

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



**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/27/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Jan/27/2021                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Withdrawal Of Consent**

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Subject No:** 12412191

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |            |
|----|---------------------|------------|
| 1. | Subject Status      | FOLLOW-UP  |
| 2. | Subject Status Date | Dec/4/2020 |

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Audit Trail](#)

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

- CRF\_Sign

| Name    | Signature Meaning | Date  | Type | Action |
|---------|-------------------|---|------|--------|
| (b) (6) | Approved          | Mar-12-2021 16:59:20 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1241

**Subject No:** 12412191

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

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

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date  | User                              | Comment        |
|------|---|-----------------------------------|----------------|
| Form | Oct-15-2020 11:12:13 (UTC-03:00) City of Buenos Aires | (b) (4),<br>(b) (6)<br>[Redacted] | Not Applicable |

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

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

- CRF\_Sign

| Name    | Signature Meaning | Date  | Type | Action |
|---------|-------------------|---|------|--------|
| (b) (6) | Approved          | Mar-12-2021 16:59:20 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-11-2021 16:13:46 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|               |          |   |      |        |
|---------------|----------|---|------|--------|
| Edson Moreira | Approved | Feb-02-2021 16:18:22 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, EdsonMoreira, 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-27-2021 15:13:08 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Affidavit:**

N/A

|               |          |   |      |        |
|---------------|----------|---|------|--------|
| Edson Moreira | Approved | Jan-22-2021 09:48:02 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------------|----------|---|------|--------|

**Affidavit:**

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

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

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



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

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

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 11:11:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>08 SEP 2020 | Initial Entry |

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

| Date  | Location        | User                | Value                                 | Reason        |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Oct-15-2020 11:11:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*I. Consent Was:*

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-15-2020 11:11:33<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 Obtain<br>ed<br><br>Oct/15/2020 | Initial Entry |

**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Subject ID**

| Date   | Location        | User                    | Value                          | Reason  |
|--|-----------------|-------------------------|--------------------------------|---|
| Nov-14-2020<br>10:46:25<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Closed                | Response satisfies query  |
| Nov-13-2020<br>13:25:16<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Answered              | AE CRF was updated.<br>Thanks!  |
| Nov-13-2020<br>09:22:41<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | Query 1: Opened                | SAE<br>RECON:AER#2020449336<br>Disorientation to<br>clarify(onset<br>date:09Nov2020)was<br>reported as serious in<br>Safety database but missing<br>in AE CRF. Please confirm<br>and update CRF. If safety<br>update is required, submit a<br>follow-up SAE Form. |
| Oct-15-2020<br>11:11:15<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>12412191 | Item copied from previous<br>form   |

**2. Birth Date:**

| Date  | Location        | User                    | Value                              | Reason           |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Oct-15-2020 11:11:13<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6) 1955 | Enrollment Entry |

**3. Sex:**

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                     |                            |               |
|---|-----------------|---------------------|----------------------------|---------------|
| Oct-15-2020 11:11:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>MALE | Initial Entry |
|---|-----------------|---------------------|----------------------------|---------------|

**4. Ethnicity:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-15-2020 11:11:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT HISPANIC OR LATINO<br>(A) OR OF SPANISH ORIGI<br>N | Initial Entry |

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

| Date  | Location        | User                | Value                       | Reason        |
|---|-----------------|---------------------|-----------------------------|---------------|
| Oct-15-2020 11:11:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*I. Date of Visit*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 11:12:02<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/15/2020 | Initial Entry |

**Header Text:** c4591001

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:52

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

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

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 11:12:30<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/15/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-15-2020 11:12:30<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        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Oct-15-2020 11:12:30<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*I.a*

| Date  | Location        | User                 | Value   | Reason        |
|---|-----------------|----------------------|---|---------------|
| Oct-15-2020 11:13:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 1<br><b>Medical History Term:</b> Hemorrhoidal disease<br><b>Start Date:</b> UNK/UNK/1980<br><b>Ongoing:</b> YES | Initial Entry |

*I.a Line/MH Number:*

| Date  | Location        | User                 | Value                   | Reason        |
|---|-----------------|----------------------|-------------------------|---------------|
| Oct-15-2020 11:13:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

*I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

| Date  | Location        | User                        | Value             | Reason   |
|---|-----------------|-----------------------------|-------------------|--|
| Nov-15-2020 18:58:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 1: Closed   | Appreciate the prompt response. Thank you.   |
| Nov-15-2020 15:15:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)         | Query 1: Answered | Revised and updated  |
| Nov-15-2020 14:42:36 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)         | Query 1: Opened   | Per case narrative, the subject has a Med hx of dyslipidemia from 2015, carotid atherosclerotic disease, |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                             |  |  |
|---|-----------------|-----------------------------|--|--|
|   |                 |                             |  | gastroesophageal reflux disease. Please revise and update this form accordingly. Thank you.  |
| Nov-15-2020<br>13:42:50 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 1: Candidate                         | Per case narrative, the subject has a Med hx of dyslipidemia from 2015, carotid atherosclerotic disease, gastroesophageal reflux disease. Please revise and update this form accordingly. Thank you. |
| Oct-15-2020 11:13:56<br>(UTC-03:00) City of Buenos Aires    | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)         | <b>Data Entry:</b><br>Hemorrhoidal disease | Initial Entry  |

***1.a Start Date:***

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-15-2020 11:13:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/1980 | Initial Entry |

***1.a Ongoing:***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-15-2020 11:13:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.b***



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Oct-15-2020 11:14:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Numb</b> 2<br><b>er:</b><br><b>Medical History</b> Allergic rhi<br><b>Term:</b> nitis<br><b>Start Date:</b> UNK/UNK/<br>2005<br><b>Ongoing:</b> YES | Initial Entry |

*1.b Line/MH Number:*

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-15-2020 11:14:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

*1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-15-2020 11:14:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Allergic rhinitis | Initial Entry |

*1.b Start Date:*

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-15-2020 11:14:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2005 | Initial Entry |

*1.b Ongoing:*

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-15-2020 11:14:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

*I.c*

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-15-2020 11:15:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 3<br><b>Medical History Term:</b> Chronic tension headache<br><b>Start Date:</b> UNK/UNK/1970<br><b>Ongoing:</b> YES | Initial Entry |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**I.c Line/MH Number:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-15-2020 11:15:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-15-2020 11:15:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Chronic tension headache | Initial Entry |

**I.c Start Date:**

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-15-2020 11:15:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/1970 | Initial Entry |

**I.c Ongoing:**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-15-2020 11:15:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**I.d**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Oct-15-2020 11:16:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH Nu 4<br>mber:<br>Medical Hist Systemic arteria<br>ory Term: 1 hypertension<br>Start Date: UNK/UNK/200<br>5 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**Ongoing:** YES***1.d Line/MH Number:***

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-15-2020 11:16:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

***1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-15-2020 11:16:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Systemic arterial hypertension | Initial Entry |

***1.d Start Date:***

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-15-2020 11:16:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2005 | Initial Entry |

***1.d Ongoing:***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-15-2020 11:16:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.e***

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-15-2020 15:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 5<br><b>Medical History Term:</b> dyslipidemi<br>a | Initial Entry |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |  |  |                                     |  |
|--|--|--|-------------------------------------|--|
|  |  |  | <b>Start Date:</b> UNK/UNK/<br>2015 |  |
|  |  |  | <b>Ongoing:</b> YES                 |  |

***I.e Line/MH Number:***

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-15-2020 15:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

***I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Nov-15-2020 15:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>dyslipidemia | Initial Entry |

***I.e Start Date:***

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Nov-15-2020 15:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2015 | Initial Entry |

***I.e Ongoing:***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-15-2020 15:12:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***I.f***

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-15-2020 15:13:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Nu 6<br/>mber:</b> | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |  |  |  |
|--|--|--|--|
|  |  |  | <b>Medical History Term:</b> carotid atherosclerotic disease<br><b>Start Date:</b> UNK/UNK/2015<br><b>Ongoing:</b> YES |
|--|--|--|--|

***1.f Line/MH Number:***

| Date  | Location        | User                 | Value                   | Reason        |
|---|-----------------|----------------------|-------------------------|---------------|
| Nov-15-2020 15:13:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>6 | Initial Entry |

***1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Nov-15-2020 15:13:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>carotid atherosclerotic disease | Initial Entry |

***1.f Start Date:***

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Nov-15-2020 15:13:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>UNK/UNK/2015 | Initial Entry |

***1.f Ongoing:***

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Nov-15-2020 15:13:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.g***

| Date                 | Location        | User      | Value              | Reason        |
|----------------------|-----------------|-----------|--------------------|---------------|
| Nov-15-2020 15:14:44 | ACV0PFEINFP6000 | auto calc | <b>Data Entry:</b> | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|                                  |  |            |  |
|----------------------------------|--|------------|--|
| (UTC-03:00) City of Buenos Aires |  | (autocalc) | Line/MH Number: 7<br>Medical History Term: gastroesophageal reflux disease<br>Start Date: UNK/UNK/2000<br>Ongoing: YES |
|----------------------------------|--|------------|--|

**1.g Line/MH Number:**

| Date  | Location        | User                 | Value                | Reason        |
|---|-----------------|----------------------|----------------------|---------------|
| Nov-15-2020 15:14:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 7 | Initial Entry |

**1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Nov-15-2020 15:14:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> gastroesophageal reflux disease | Initial Entry |

**1.g Start Date:**

| Date  | Location        | User             | Value                           | Reason        |
|---|-----------------|------------------|---------------------------------|---------------|
| Nov-15-2020 15:14:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> UNK/UNK/2000 | Initial Entry |

**1.g Ongoing:**

| Date  | Location        | User             | Value                  | Reason        |
|---|-----------------|------------------|------------------------|---------------|
| Nov-15-2020 15:14:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> YES | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** HIV STATUS - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Select appropriate response - What is the subject HIV status?*

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-15-2020 11:19:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>The subject is NOT known to<br>be HIV POSITIVE | Initial Entry |



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/15/2020 | Initial Entry |

**2. Weight:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>78.5 | Initial Entry |

**3. Unit:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>kg | Initial Entry |

**4. Height:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>165.0 | Initial Entry |

**5. Unit:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>cm | Initial Entry |

**6. Body Mass Index:**

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>28.8 | Initial Entry |

7.a

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b><br>36.4<br><b>Temperature Unit:</b><br>ORAL CATHETER | Initial Entry |

7.a Record Identifier:

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-15-2020 11:20:46<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        |
|--|-----------------|---------------------|----------------------------|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>36.4 | Initial Entry |

7.a Unit:

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-15-2020 11:20:46<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:

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 11:20:46<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12412191

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

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

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Randomization Date :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 11:21:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/15/2020 | Initial Entry |

**2. Randomization Number:**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 11:21:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>269363 | Initial Entry |

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-16-2020 08:31:31<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-16-2020 08:31:31<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-16-2020 08:31:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Oct-16-2020 08:31:31<br>(UTC-03:00) City of<br>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-16-2020 08:31:31<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>Oct/15/2020 | Initial Entry  |

**5.a**

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

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, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |                 |                     |  |               |
|--|-----------------|---------------------|--|---------------|
| Oct-16-2020 08:31:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPTSPW | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5.a Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-16-2020 08:31:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPTSPW | Initial Entry |

5.b

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-16-2020 08:31:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BMM6T7 | Initial Entry |

5.b Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-16-2020 08:31:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BMM6T7 | Initial Entry |

5.c

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-16-2020 08:32:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BMM6T8 | Initial Entry |

5.c Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-16-2020 08:32:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BMM6T8 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (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, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-16-2020 07:21:21<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-16-2020 07:21:21<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-16-2020 07:21:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Oct-16-2020 07:21:21<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-16-2020 07:21:21<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>Oct/15/2020 | Initial Entry  |

**5.a**

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

**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, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |  |               |
|--|-----------------|---------------------|--|---------------|
| Oct-16-2020 07:21:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BRD41X | Initial Entry |
|--|-----------------|---------------------|--|---------------|

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-16-2020 07:21:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BRD41X | Initial Entry |



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12412191

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-15-2020 11:21:28<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        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-15-2020 11:21:28<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        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-15-2020 11:21:28<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        |
|--|-----------------|---------------------|---|---------------|
| Oct-15-2020 11:21:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/15/2020 08:54 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-15-2020 11:21:28<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:**

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Oct-15-2020 11:21:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-15-2020 11:21:28<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        |
|--|-----------------|-------------------------|--|---------------|
| Oct-15-2020 11:21:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED<br>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        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-15-2020 11:21:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-15-2020 11:21:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO - REACTOGENICITY E-<br>DIARY NOT COLLECTED F<br>OR THIS SUBJECT | Initial Entry |

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1241**Subject No:** 12412191**Generated By:** (b) (4)**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**I. Date of Visit**

| Date   | Location        | User                | Value                    | Reason  |
|--|-----------------|---------------------|--------------------------|---|
| Nov-19-2020 03:28:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed          | Response satisfies query  |
| Nov-18-2020 08:38:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered        | This alert refers to the Covid visit of 12Nov2020   |
| Nov-18-2020 03:56:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Reissued:Opened | RQ1: Thank you for the response. Please consider to follow-up and confirm for reported Illness eDiary response on 13NOV2020. Please update or clarify.  |
| Nov-17-2020 10:43:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered        | The subject was asked by the site to make the notification, which only occurred after Covid's visit   |
| Nov-17-2020 08:00:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Opened          | Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the COVID-19 symptoms or diagnosis on 13NOV2020. But no corresponding COVID Illness visit indicate symptoms present |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                                  |  |
|--|-----------------|---------------------|----------------------------------|--|
|  |                 |                     |                                  | at this date. Pls update Covid illness visit or clarify. |
| Nov-06-2020 10:15:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/6/2020 | Initial Entry  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Oct-2020 16:01**Site No:** 1241**Subject No:** 12412191**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Date:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-06-2020 10:15:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/6/2020 | Initial Entry |

**2.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-06-2020 10:15:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b><br><b>Temperature:</b> 36.4<br><b>Temperature Unit:</b><br><b>Temperature Location:</b> ORAL CAVITY | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-06-2020 10:15:45<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        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-06-2020 10:15:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>36.4 | Initial Entry |

**2.a Unit:**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                     |                         |               |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-06-2020 10:15:45<br>(UTC-03:00) City of<br>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        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-06-2020 10:15:45<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-06-2020 11:07:57<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        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-06-2020 11:07:57<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   |
|--|-----------------|---------------------------|--|--|
| Nov-06-2020 11:08:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Nov-06-2020 11:07:57<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. |
| Nov-06-2020 11:07:57<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>Nov/6/2020 | Initial Entry  |

**5.a**

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



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |  |               |
|--|-----------------|---------------------|--|---------------|
| Nov-06-2020 11:08:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BR5TY4 | Initial Entry |
|--|-----------------|---------------------|--|---------------|

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-06-2020 11:08:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR5TY4 | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12412191

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-06-2020 10:16:14<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        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-06-2020 10:16:14<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        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Nov-06-2020 10:16:14<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        |
|--|-----------------|---------------------|--|---------------|
| Nov-06-2020 10:16:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/6/2020 09:22 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-06-2020 10:16:14<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:**

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-06-2020 10:16:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-06-2020 10:16:14<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        |
|--|-----------------|-------------------------|--|---------------|
| Nov-06-2020 10:16:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED<br>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        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-06-2020 10:16:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*I. Date of Visit*

| Date  | Location        | User                | Value                            | Reason        |
|---|-----------------|---------------------|----------------------------------|---------------|
| Dec-04-2020 11:19:11<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/4/2020 | 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, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-04-2020 13:54:17<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-04-2020 13:54:17<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   |
|--|-----------------|---------------------------|--|--|
| Dec-04-2020 13:54:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Dec-04-2020 13:54:17<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-04-2020 13:54:17<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>Dec/4/2020 | Initial Entry  |

**5.a**

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

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |                 |                     |  |               |
|--|-----------------|---------------------|--|---------------|
| Dec-04-2020 13:54:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BR7CBM | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5.a Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-04-2020 13:54:26<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR7CBM | Initial Entry |

5.b

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-04-2020 13:54:35<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BS2KH1 | Initial Entry |

5.b Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-04-2020 13:54:35<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2KH1 | Initial Entry |

5.c

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-04-2020 13:54:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BS2KH2 | Initial Entry |

5.c Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-04-2020 13:54:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2KH2 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

***1. Date of Visit***

| Date  | Location        | User                | Value             | Reason  |
|---|-----------------|---------------------|-------------------|---|
| Dec-24-2020<br>06:58:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 4: Closed   | Closed as data entered.   |
| Dec-23-2020<br>11:16:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 4: Answered | data updated  |
| Dec-23-2020<br>10:16:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 4: Opened   | DM: Kindly review and complete 'Hospitalization Details form' at this visit. Thank you.               |
| Nov-17-2020<br>09:11:11 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 3: Closed   | Response satisfies query  |
| Nov-16-2020<br>15:27:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 3: Answered | data updated  |
| Nov-16-2020<br>07:22:10<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 3: Opened   | DM: Kindly review and complete 'Microbiology Specimen Illness Details form' at this visit. Thank you. |
| Nov-13-2020   | ACV0PFEINFP6000 | auto query          | Query 1: Deleted  | Close Auto Query  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**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:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                           |                                   |  |
|--|-----------------|---------------------------|-----------------------------------|--|
| 14:17:11<br>(UTC-03:00) City of<br>Buenos Aires                |                 | (autoquery)               |                                   |  |
| Nov-13-2020<br>14:13:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Deleted                  | Close Auto Query   |
| Nov-13-2020<br>14:12:55<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Candidate                | Date of Visit is<br>completed but Date<br>of Assessment in<br>the Signs and<br>Symptoms form is<br>missing. Please<br>review and update<br>as appropriate.             |
| Nov-13-2020<br>14:12:55<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate                | Date of Visit is<br>completed but Date<br>of Collection in<br>both Nasal Swab<br>Self and Nasal<br>Swab are missing.<br>Please review and<br>update as<br>appropriate. |
| Nov-13-2020<br>14:12:55<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry  |

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

| Date  | Location        | User                    | Value                         | Reason        |
|---|-----------------|-------------------------|-------------------------------|---------------|
| Nov-13-2020 14:12:55<br>(UTC-03:00) City of<br>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 Nov/12/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Date of Assessment:**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry |

**2. Date of First Symptom Started:**

| Date  | Location        | User                | Value                            | Reason        |
|---|-----------------|---------------------|----------------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/9/2020 | Initial Entry |

**3. Symptoms Ongoing?**

| Date  | Location        | User                | Value              | Reason   |
|---|-----------------|---------------------|--------------------|--|
| Dec-23-2020 09:43:08<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed    | Response satisfies<br>query  |
| Dec-22-2020 09:55:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered  | data updated   |
| Dec-21-2020 17:01:33<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened    | As per source<br>data, participant<br>reported other<br>symptoms as<br>disorientation and<br>transient global<br>amnesia. Please<br>review source data<br>and consider<br>update information<br>as applicable. |
| Nov-13-2020 14:18:53  | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b> | Transcription  |

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                     |   |               |
|---|-----------------|---------------------|---|---------------|
| (UTC-03:00) City of Buenos Aires                      |                 | (b) (4),<br>(b) (6) | NO<br>Date of Last Symptom Resolved:<br><br>Nov/10/2020 | Error         |
| Nov-13-2020 14:13:36 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES                               | Initial Entry |

**4.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(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        |
|---|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 14:13:36 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**4.a Was symptom present?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:13:36 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.b**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:13:36 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom</b> NEW OR INCREASED COUGH<br><b>Symptom Present:</b> NO | Initial Entry |

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

4.b Symptoms:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.c

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Symptom: NEW OR INCREASED SHORTNESS OF BREATH<br>Symptom Present: NO | Initial Entry |

4.c Symptoms:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

4.d

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> CHILLS<br><b>Symptom Present:</b> NO | Initial Entry |

4.d Symptoms:

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

4.d Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.e

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN<br><b>Symptom Present:</b> NO | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

4.e Symptoms:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED MUS<br>CLE PAIN | Initial Entry |

4.e Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.f

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom</b> NEW LOSS OF T<br>s:       ASTE OR SMEL<br>L<br><b>Symptom</b> NO<br><b>Present:</b> | Initial Entry |

4.f Symptoms:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW LOSS OF TASTE OR S<br>MELL | Initial Entry |

4.f Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

4.g

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCRE<br>ASED SORE THR<br>OAT<br><b>Symptom Present:</b> NO | Initial Entry |

4.g Symptoms:

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SOR<br>E THROAT | Initial Entry |

4.g Was symptom present?

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.h

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> DIARRHE<br>A<br><b>Symptom Present:</b> NO | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

4.h Symptoms:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.i

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> VOMITIN<br>G<br><b>Symptom Present:</b> YES | Initial Entry |

4.i Symptoms:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

4.i Was symptom present?

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-13-2020 14:13:36<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

5.a

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:14:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Symptoms - Other Dizziness | Initial Entry |

*5.a Symptoms - Other Text:*

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Nov-13-2020 14:14:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dizziness | Initial Entry |

*5.b*

| Date   | Location        | User                | Value  | Reason              |
|--|-----------------|---------------------|--|---------------------|
| Dec-22-2020 11:36:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Symptoms - Other: Disorientation | Transcription Error |
| Dec-22-2020 09:55:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Symptoms - Other: Desorientation | Initial Entry       |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.b Symptoms - Other Text:**

| Date   | Location                                  | User                        | Value  | Reason  |
|--|---|-----------------------------|--|---|
| Dec-22-2020<br>12:54:02<br>(UTC-03:00)<br>City of<br>Buenos<br>Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS<br>Oracle<br>(b) (4) | Query<br>1: Clo<br>sed                               | Discrepancy has<br>been closed.   |
| Dec-22-2020<br>11:36:38<br>(UTC-03:00)<br>City of<br>Buenos<br>Aires | ACV0PFEINFP6000                           | auto query<br>(autoquery)   | Query<br>1: An<br>swere<br>d                         | Transcription Error   |
| Dec-22-2020<br>11:36:38<br>(UTC-03:00)<br>City of<br>Buenos<br>Aires | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)         | <b>Data<br/>Entry</b><br>:<br>Disori<br>entati<br>on | Transcription Error   |
| Dec-22-2020<br>10:52:04<br>(UTC-03:00)<br>City of<br>Buenos<br>Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS<br>Oracle<br>(b) (4) | Query<br>1: Op<br>ened                               | Clarify<br>DESORIENTATION<br>as follows...Should<br>the spelling be<br>DISORIENTATION?<br>If so, edit. Otherwise<br>clarify. Thank you. |
| Dec-22-2020<br>09:55:18<br>(UTC-03:00)<br>City of<br>Buenos<br>Aires | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)         | <b>Data<br/>Entry</b><br>:<br>Desor<br>ientati<br>on | Initial Entry   |

**5.c**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Dec-22-2020 09:55:39<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms -</b> Transient globa<br><b>Other:</b> I amnesia | Initial Entry |
|---|-----------------|---------------------|--|---------------|

**5.c Symptoms - Other Text:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-22-2020 09:55:39<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Transient global amnesia | Initial Entry |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-16-2020 15:27:18<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 on Nov/12/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Actual Date of Collection:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 15:27:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/10/2020 | Initial Entry |

**2. Specimen Type:**

| Date   | Location        | User                | Value                                  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 15:27:18<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        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 15:27:18<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        |
|--|-----------------|-------------------------|--|---------------|
| Nov-16-2020 15:27:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SEVERE ACUTE RESP SYN<br>DROME CORONAVIRUS 2 | Initial Entry |

**5. Device Type:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-16-2020 15:27:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SARS-COV-2 DIAGNOSTIC T<br>EST | Initial Entry |

**6. Trade Name:**

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| Date  | Location        | User                | Value                       | Reason        |
|---|-----------------|---------------------|-----------------------------|---------------|
| Nov-16-2020 15:27:18<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>OTHER | Initial Entry |

**7. Test Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 15:27:18<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEGATIVE | Initial Entry |

**9. Trade Name Other, Specify:**

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Nov-16-2020 15:27:18<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NALT unknown | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1241**Subject No:** 12412191**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-13-2020 14:16:42<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        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-13-2020 14:16:42<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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:16:42<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        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:16:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Subject used site swab | Initial Entry |

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**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:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-13-2020 14:17:11<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        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Nov-13-2020 14:17:11<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value   | Reason   |
|---|-----------------|---------------------------|---|--|
| Nov-13-2020 14:17:23<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Nov-13-2020 14:17:11<br>(UTC-03:00) City of<br>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. |
| Nov-13-2020 14:17:11<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>Nov/12/2020 | Initial Entry  |

**5.a**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:17:23<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BR6696 | Initial Entry |
|---|-----------------|---------------------|--|---------------|

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-13-2020 14:17:23<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR6696 | Initial Entry |



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Not Complete**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**I.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> SPECIALIST<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

**I.a Physician or Healthcare Professional:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-13-2020 14:18:04<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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:18:04<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        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> EMERGENCY ROOM<br><b>Occurrence of Visits or Contacts:</b> YES<br><i>Number of Visits or Contacts:</i><br>1 | Initial Entry |

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Not Complete**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09***1.b Physician or Healthcare Professional:***

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>EMERGENCY ROOM | Initial Entry |

***1.b Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br><i>Number of Visits or Contacts</i><br>:<br><br>1 | Initial Entry |

***1.c***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(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 |

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Not Complete**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12412191**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09***I.c Physician or Healthcare Professional:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>PRIMARY CARE PHYSICIAN | Initial Entry |

***I.c Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***I.d***

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(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        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>URGENT CARE | Initial Entry |

***I.d Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***I.e***

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Not Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(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 |

*I.e Physician or Healthcare Professional:*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>TELEPHONE CONSULTATION | Initial Entry |

*I.e Occurrence of Visits or Contacts:*

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*I.f*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> OTHER<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Not Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

***1.f Physician or Healthcare Professional:***

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 14:18:04<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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:18:04<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   |
|--|-----------------|---------------------------|---|--|
| Dec-23-2020 09:42:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed   | Response satisfies query   |
| Dec-22-2020 09:57:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered   | New Information  |
| Dec-22-2020 09:57:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Has the subject been in intensive care due to potential COVID-19 illness?<br><br>YES | New Information  |
| Dec-21-2020 16:51:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened   | As per source data, participant was in intensive care due to potential covid-19 illness from 09Nov2020 to 12Nov2020, SAE |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Not Complete

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                          |  |
|--|-----------------|---------------------|--------------------------|--|
|  |                 |                     |                          | 2020449336 reported. Please review source documents and consider update information as applicable. CRF section 8.35 for reference. |
| Nov-13-2020 14:18:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry  |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Dec-23-2020 11:16:17<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 on Nov/12/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Hospitalization Category:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-23-2020 11:16:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HOSPITALIZATION STATUS | Initial Entry |

**2. Hospitalization Term:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-23-2020 11:16:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>HOSPITAL | Initial Entry |

**3. Admission Date:**

| Date   | Location        | User                | Value                            | Reason  |
|--|-----------------|---------------------|----------------------------------|---|
| Mar-12-2021 15:01:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened                  | CLIQUEY:<br>Hospitalization:<br>This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information. |
| Dec-23-2020 11:16:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/9/2020 | Initial Entry   |

**4. Ongoing?**

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Queries

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-23-2020 11:16:17<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>Discharge Date:<br><br>Nov/12/2020 | Initial Entry |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Category of Clinical Event:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-16-2020 13:48:20<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>POTENTIAL COVID-19 ILLN<br>ESS | Initial Entry |

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-16-2020 13:48:20<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Toxicity Grade:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-16-2020 13:48:20<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/13/2021

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

**Site No:** 1241

**Subject No:** 12412191

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

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

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date of Visit**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-13-2021 11:21:28<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Jan/13/2021 | Initial Entry |

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

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-13-2021 11:21:28<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COVID_A1 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/13/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1241**Subject No:** 12412191**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-13-2021 13:53:02<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-13-2021 13:53:02<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-13-2021 13:53:13<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Jan-13-2021 13:53:02<br>(UTC-03:00) City of<br>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. |
| Jan-13-2021 13:53:02<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>Jan/13/2021 | Initial Entry  |

**5.a**

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

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/13/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Jan-13-2021 13:53:13<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPTKMF | Initial Entry |
|---|-----------------|---------------------|--|---------------|

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-13-2021 13:53:13<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPTKMF | Initial Entry |

**5.b**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Jan-13-2021 13:54:29<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BRT721 | Initial Entry |

**5.b Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-13-2021 13:54:29<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BRT721 | Initial Entry |

**5.c**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Jan-13-2021 13:54:37<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BRT722 | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-13-2021 13:54:37<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BRT722 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-13-2020 13:23:44<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:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Mar-11-2021 16:13:46<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:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Mar-11-2021 16:17:06<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:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Mar-11-2021 16:19:09<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: 1241

Subject No: 12412191

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-13-2020 13:23:44<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        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-13-2020 13:23:44<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  |
|--|-----------------|-----------------------------|---------------------------|---|
| Feb-25-2021 13:11:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 2: Closed           | Escalated to CRA  |
| Feb-19-2021 16:07:34<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)         | Query 2: Answered         | Diagnosis not available. Subject is under evaluation with neurologist.  |
| Jan-15-2021 12:05:54<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 2: Reissued:Open ed | Thanks for confirming. Please make every effort possible to obtain further information and respond to the query once additional information is available. |
| Jan-15-2021 10:07:06<br>(UTC-03:00) City of              | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)         | Query 2: Answered         | Subject attended to visit the site on 13Jan2021 but to  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                             |                           |   |
|---|-----------------|-----------------------------|---------------------------|---|
| Buenos Aires  |                 |                             |                           | close the event depends on the result of magnetic resonance that is scheduled for 16Jan2021   |
| Dec-23-2020<br>20:37:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 2: Reissued:Open ed | Kindly clarify if the disorientation was a symptom of the transition global amnesia, was the later considered the final diagnosis? If so, please consider updating AE to final diagnosis. |
| Dec-23-2020<br>10:41:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)         | Query 2: Answered         | All symptoms reported to safety (dizziness, vomiting, transitional global amnesia) are related to AE "Disorientation to clarify". Is not consider new AE.                                 |
| Dec-15-2020<br>12:24:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 2: Opened           | Per SAE report submitted to safety, the subject has a specific diagnosis of "Transitional global amnesia". Kindly revise as an additional AE and update the log accordingly. Thank you    |
| Dec-15-2020<br>12:20:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 1: Closed           | I am closing due to a new query being issued.   |
| Dec-03-2020   | ACV0PFEINFP6000 | Giselle Castillo            | Query 1: Reissued:Open    | Appreciate the  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1241**Subject No:** 12412191**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                             |                           |  |
|---|-----------------|-----------------------------|---------------------------|--|
| 17:02:16<br>(UTC-03:00) City of Buenos Aires                |                 | (b) (4)                     | ed                        | response. Kindly further elaborate on the reason for the lack of diagnosis. Please make every effort to obtain these information. Thank you.   |
| Dec-03-2020<br>15:41:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)            | Query 1: Answered         | DIAGNOSIS NOT AVAILABLE  |
| Nov-25-2020<br>13:16:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 1: Reissued:Open ed | Thanks for confirming. Please respond to the query once additional information is available. Thanks  |
| Nov-24-2020<br>15:30:12<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)         | Query 1: Answered         | A FOLLOW UP REPORT WAS SENT TO SAFETY WITH THE RESULT FOR SARS-COV-2 AS NOT DETECTED ON 17NOV2020. DIAGNOSIS NOT AVAILABLE UNTIL THE PRESENT MOMENT.   |
| Nov-20-2020<br>20:07:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Giselle Castillo<br>(b) (4) | Query 1: Opened           | Per case narrative, "The diagnosis of the SAE was pending, and it was suspected as SARS-COV2 or ischemic cerebrovascular disease or viral meningoencephalitis." Kindly provide current diagnosis and |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12412191

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

|   |                 |                  |   |   |
|---|-----------------|------------------|---|---|
|   |                 |                  |   | submit FU report with updated information. Thank you. |
| Nov-13-2020 13:23:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Disorientation to clarify | Initial Entry   |

4. Start Date Time:

| Date  | Location        | User             | Value                                    | Reason        |
|---|-----------------|------------------|--|---------------|
| Nov-13-2020 13:23:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Nov/9/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Nov-13-2020 13:23:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Nov/12/2020 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-13-2020 13:23:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>3 | 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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                           |   |  |
|---|-----------------|---------------------------|---|--|
| Nov-14-2020<br>10:44:39 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Nov-13-2020<br>13:23:44 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | For AE<br>Disorientation to<br>clarify: Response<br>to "Is the adverse<br>event serious?" is<br>'Yes' but "Serious<br>Adverse Event<br>Number" is blank. |
| Nov-13-2020<br>13:23:44 (UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Is this serious event associ-<br>ated with congenital anom-<br>aly or birth defect?<br><br>NO<br><br>Did this serious event resu-<br>lt in death?<br><br>NO<br><br>Did this serious event requ-<br>ire or prolong hospitalizati-<br>on?<br><br>YES<br><br>Did this serious event resu-<br>lt in persistent or signifi-<br>cant disability/incapacity?<br><br>NO<br><br>Is this serious event life th-<br>reatening?<br><br>NO<br><br>Other medically important | Initial Entry  |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12412191

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

|  |  |  |               |  |
|--|--|--|---------------|--|
|  |  |  | serious event |  |
|  |  |  | NO            |  |

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 13:23:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 13:23:44<br>(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<br><br><i>If Other, specify:</i><br><br>to clarify | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-13-2020 13:23:44<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        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-13-2020 13:23:44<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

12. Was a Non-Drug Treatment given?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 13:23:44<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        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 13:23:44<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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 13:23:44<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        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-14-2020 10:44:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>2020449336 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12412191

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-11-2021 16:13:46<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        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Mar-11-2021 16:13:46<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-12-2021 11:43:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Opened                | Clin: Per Prot Sect 8.3.7., COVID-19 listed symptoms VOMITING does not qualify as AE and please should be documented only on the COVID-19 Illness CRF SOD form (already entered) and should not be captured on the AE CRF page |
| Mar-11-2021 16:13:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | <b>Data Entry:</b><br>Vomiting | Initial Entry  |

**4. Start Date Time:**

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                | Value                                    | Reason        |
|--|-----------------|---------------------|--|---------------|
| Mar-11-2021 16:13:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/9/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-11-2021 16:13:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Nov/10/2020 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

| Date   | Location        | User                | Value                   | Reason              |
|--|-----------------|---------------------|-------------------------|---------------------|
| Mar-11-2021 16:14:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>3 | Transcription Error |
| Mar-11-2021 16:13:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>4 | 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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Mar-11-2021 16:13:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

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

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Mar-11-2021 16:13:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-11-2021 16:13:46<br>(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<br><br><i>If Other, specify:</i><br><br>Unknown | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Mar-11-2021 16:13:46<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        |
|--|-----------------|---------------------|---------------------------|---------------|
| Mar-11-2021 16:13:46<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-11-2021 16:13:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Queries

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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

| Date  | Location        | User                | Value                                    | Reason        |
|---|-----------------|---------------------|--|---------------|
| Mar-11-2021 16:13:46<br>(UTC-03:00) City of<br>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-11-2021 16:13:46<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12412191

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-11-2021 16:17:06<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-11-2021 16:17:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Mar-11-2021 16:17:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dizziness | Initial Entry |

**4. Start Date Time:**

| Date   | Location        | User                | Value                                    | Reason        |
|--|-----------------|---------------------|--|---------------|
| Mar-11-2021 16:17:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/9/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-11-2021 16:17:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Nov/10/2020 UNK:UNK | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12412191

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

6. Toxicity Grade:

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Mar-11-2021 16:17:06<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?

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-11-2021 16:17:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Mar-11-2021 16:17:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Mar-11-2021 16:17:06<br>(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<br><br>If Other, specify:<br><br>Unknown | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Mar-11-2021 16:17:06<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-11-2021 16:17:06<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-11-2021 16:17:06<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-11-2021 16:17:06<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-11-2021 16:17:06<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12412191

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-11-2021 16:19:09<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-11-2021 16:19:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-11-2021 16:19:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Transitional global amnesia | Initial Entry |

**4. Start Date Time:**

| Date   | Location        | User                | Value                                    | Reason        |
|--|-----------------|---------------------|--|---------------|
| Mar-11-2021 16:19:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/9/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-11-2021 16:19:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Nov/11/2020 UNK:UNK | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

6. Toxicity Grade:

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Mar-11-2021 16:19:09<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?

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-11-2021 16:19:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Mar-11-2021 16:19:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Mar-11-2021 16:19:09<br>(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<br><br>If Other, specify:<br><br>Unknown | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12412191

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Mar-11-2021 16:19:09<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-11-2021 16:19:09<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-11-2021 16:19:09<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-11-2021 16:19:09<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-11-2021 16:19:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

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

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Dec-04-2020 11:19:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/4/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-04-2020 11:19:48<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        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Dec-04-2020 11:19:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Date of Visit*

| Date  | Location        | User   | Value                             | Reason        |
|---|-----------------|--|-----------------------------------|---------------|
| Jan-27-2021 15:13:18<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted]<br>[Redacted] | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry |

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

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

| Date  | Location        | User   | Value  | Reason        |
|---|-----------------|--|--|---------------|
| Jan-27-2021 15:13:35<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted]<br>[Redacted] | <b>Data Entry:</b><br>Participant is willing to return for Vaccination 3<br>Participant is:<br><br>eligible and NOT confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1241

**Subject No:** 12412191

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date Treatment Unblinded :**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Jan-27-2021 15:13:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Jan-27-2021 15:13:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Subject Status**

| Date   | Location        | User                    | Value                                     | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-04-2020 11:19:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Oct-15-2020 11:21:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Oct-15-2020 11:12:30<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        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-04-2020 11:19:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Dec/4/2020  | Initial Entry |
| Oct-15-2020 11:21:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/15/2020 | Initial Entry |
| Oct-15-2020 11:12:30<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/15/2020 | Initial Entry |

090177e196ae3f51\Final\Final On: 01-Apr-2021 05:16 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12412191

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Casebook Signature*

| Date  | Location        | User                        | Value                                      | Reason        |
|---|-----------------|-----------------------------|--|---------------|
| Jan-22-2021 09:47:55<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | Edson<br>Moreira<br>(b) (4) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |