

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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 | 30 JUN 2020 |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/19/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [12411269] |
| 2. | Birth Date: | (b) (6) 1977 |
| 3. | Sex: | MALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | BLACK OR AFRICAN AMERICAN |
| 6. | Racial Designation: | |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 | Aug/19/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

eCRF Audit Trail History

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

| | | |
|-----|-------------------------------------|--|
| 1.a | Inclusion Number: | 1 |
| | Criterion Description: | Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) |
| | Criterion met? | YES |
| | Criterion ID: (For Pfizer use only) | IN01A00 |
| 1.b | Inclusion Number: | 2 |
| | Criterion Description: | Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures |
| | Criterion met? | YES |
| | Criterion ID: (For Pfizer use only) | IN02A00 |
| 1.c | Inclusion Number: | 3 |
| | Criterion Description: | Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study |
| | Criterion met? | YES |
| | Criterion ID: (For Pfizer use only) | IN03A00 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

| | | |
|-----|-------------------------------------|---|
| 1.d | Inclusion Number: | 4 |
| | Criterion Description: | Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol |
| | Criterion met? | YES |
| | Criterion ID: (For Pfizer use only) | IN04A00 |

Exclusion Criteria

| | | |
|-----|-------------------------------------|---|
| 2.a | Exclusion Number: | 1 |
| | Criterion Description: | Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX01A00 |

| | | |
|-----|-------------------------------------|--|
| 2.b | Exclusion Number: | 2 |
| | Criterion Description: | Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX02A00 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

| | | |
|-----|-------------------------------------|--|
| 2.c | Exclusion Number: | 3 |
| | Criterion Description: | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX03A00 |
| 2.d | Exclusion Number: | 4 |
| | Criterion Description: | Receipt of medications intended to prevent COVID-19 |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX04A00 |
| 2.e | Exclusion Number: | 8 |
| | Criterion Description: | Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX08A00 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-----|-------------------------------------|---|
| 2.f | Exclusion Number: | 10 |
| | Criterion Description: | Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX10A00 |
| 2.g | Exclusion Number: | 11 |
| | Criterion Description: | Women who are pregnant or breastfeeding |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX11A00 |
| 2.h | Exclusion Number: | 12 |
| | Criterion Description: | Previous vaccination with any coronavirus vaccine |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX12A00 |
| 2.i | Exclusion Number: | 13 |
| | Criterion Description: | Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX13A01 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-----|-------------------------------------|---|
| 2.j | Exclusion Number: | 15 |
| | Criterion Description: | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX14A01 |
| 2.k | Exclusion Number: | 16 |
| | Criterion Description: | Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX15A01 |
| 2.1 | Exclusion Number: | 17 |
| | Criterion Description: | Previous participation in other studies involving study intervention containing lipid nanoparticles |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX16A01 |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-----|-------------------------------------|---|
| 2.m | Exclusion Number: | 22 |
| | Criterion Description: | Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members |
| | Criterion met? | NO |
| | Criterion ID: (For Pfizer use only) | EX21A01 |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, 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 | Aug/19/2020 |
| 2. | Phase of Disposition: | SCREENING |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, 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: | [Vasectomy] |
| | Start Date: | UNK/UNK/2016 |
| | Ongoing: | NO End Date: UNK/UNK/2016 |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, 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: | Aug/19/2020 |
| 2. | Weight: | [128.2] |
| 3. | Unit: | kg |
| 4. | Height: | [173.0] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [42.8] |

Vital Signs Details

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

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Aug/19/2020 |
| 2. | Randomization Number: | [55770] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 Date of Collection: Aug/19/2020 |
| 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 | [BP5S7X] |
| 5.b | Sample ID | [BP5S7Y] |
| 5.c | Sample ID | [BP5S7Z] |
| 5.d | Sample ID | [BLCHF0] |
| 5.e | Sample ID | [BLCHF1] |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 Date of Collection: Aug/19/2020 |
| 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 | [BP5S87] |
|-----|-----------|----------|

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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: | Aug/19/2020 10:59 |
| 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 |

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, 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 |
|----|---|---|

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 | Sep/9/2020 |
| 2. | Erroneous Visit | |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Sep/9/2020 |
|----|-------|------------|

Vital Signs Details

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 Date of Collection: Sep/9/2020 |
| 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 | [BPX0RJ] |
|-----|-----------|----------|

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, 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: | Sep/9/2020 10:42 |
| 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 |

090177e196ae3f4f\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, Locked, Frozen, Verified

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

Subject No: 12411269 **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 | Oct/8/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12411269 **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 Date of Collection: Oct/8/2020 |
| 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 | [BPWXXM] |
| 5.b | Sample ID | [BHJ01H] |
| 5.c | Sample ID | [BHJ01J] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

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 | Oct/23/2020 |
| 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 Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

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](#)

Signs and Symptoms

| | | |
|----|--------------------------------|---|
| 1. | Date of Assessment: | Oct/23/2020 |
| 2. | Date of First Symptom Started: | Oct/17/2020 |
| 3. | Symptoms Ongoing? | NO Date of Last Symptom Resolved: Oct/25/2020 |

Symptoms

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-------------------------|------------------------|------------------------------|
| 4.f | Symptoms: | NEW LOSS OF TASTE OR SMELL |
| | Was symptom present? | YES |
| 4.g | Symptoms: | NEW OR INCREASED SORE THROAT |
| | Was symptom present? | NO |
| 4.h | Symptoms: | DIARRHEA |
| | Was symptom present? | YES |
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | YES |
| Symptoms - Other | | |
| 5.a | Symptoms - Other Text: | [Asthenia] |
| 5.b | Symptoms - Other Text: | [Abdominal discomfort] |
| 5.c | Symptoms - Other Text: | [Nausea] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

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: 12411269

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. | Oct/24/2020 | SWABBED MATERIAL | NASOPHARYNX | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

| | | |
|----|-------------------------------|--|
| 1. | Actual Date of Collection: | Oct/24/2020 |
| 2. | Specimen Type: | SWABBED MATERIAL |
| 3. | Specimen Collection Location: | NASOPHARYNX |
| 4. | Assay Code and Description: | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 |
| 5. | Device Type: | SARS-COV-2 DIAGNOSTIC TEST |
| 6. | Trade Name: | ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2 |
| 7. | Test Result: | NEGATIVE |
| 8. | Comments/Findings /Details: | [] |
| 9. | Trade Name Other, Specify: | [] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

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_SELF |
| 3. | Sample Collected? | YES Date of Collection: Oct/23/2020 |
| 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 | [RW92873] |
|-----|-----------|-----------|

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

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? | NO |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [Subject used self swab] |

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 Number of Visits or Contacts: [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 |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-----|---------------------------------------|-------|
| 1.f | Physician or Healthcare Professional: | OTHER |
| | Occurrence of Visits or Contacts: | NO |

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

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: 12411269

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. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

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: | 1 |

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: 12411269

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. | | | | | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

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

Lab Result

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

090177e196ae3f4f\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: 30-Jul-2020 21:28

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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. | | | | | | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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. | | | | | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

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/8/2021 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

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](#)

Signs and Symptoms

| | | |
|----|--------------------------------|--|
| 1. | Date of Assessment: | Jan/8/2021 |
| 2. | Date of First Symptom Started: | Jan/6/2021 |
| 3. | Symptoms Ongoing? | NO Date of Last Symptom Resolved: Jan/9/2021 |

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? | YES |
| 4.e | Symptoms: | NEW OR INCREASED MUSCLE PAIN |
| | Was symptom present? | NO |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-------------------------|------------------------|------------------------------|
| 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? | YES |
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | NO |
| Symptoms - Other | | |
| 5.a | Symptoms - Other Text: | [Nausea] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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. | Jan/9/2021 | SWABBED MATERIAL | NASOPHARYNX | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Microbiology Specimen

| | | |
|----|-------------------------------|--|
| 1. | Actual Date of Collection: | Jan/9/2021 |
| 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: | ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2 |
| 7. | Test Result: | NEGATIVE |
| 8. | Comments/Findings /Details: | [] |
| 9. | Trade Name Other, Specify: | [] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021**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:** 12411269**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 | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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 Date of Collection: Jan/8/2021 |
| 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 | [BR798F] |
|-----|-----------|----------|

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: | NO |
| 1.c | Physician or Healthcare Professional: | PRIMARY CARE PHYSICIAN |
| | Occurrence of Visits or Contacts: | NO |
| 1.d | Physician or Healthcare Professional: | URGENT CARE |
| | Occurrence of Visits or Contacts: | NO |
| 1.e | Physician or Healthcare Professional: | TELEPHONE CONSULTATION |
| | Occurrence of Visits or Contacts: | NO |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-----|---------------------------------------|-------|
| 1.f | Physician or Healthcare Professional: | OTHER |
| | Occurrence of Visits or Contacts: | NO |

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 06-Jul-2020 21:52

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: ILLNESS DETAILS

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](#)

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: | 1 |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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. | | | | | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

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

Lab Result

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| # | Category f or Lab Tes t | Vendor Nam e (DERIVED) | Collecti on Date : | Specim en Type | Lab Result | | | Form Instan ce |
|----|-------------------------------|-------------------------------|--------------------------|-------------------|------------------------------------|-----------|-------------|-------------------------------------|
| 1. | | | | | Sponsor-Defi ned Identifie r | Te st: | Res ult: | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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. | | | | | | Repeating Pages |

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 06-Jul-2020 21:55

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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Concomitant Medications

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

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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. | | | | | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/20/2020

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: 12411269

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/20/2020 |
| 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 Nov/20/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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 Date of Collection: Nov/20/2020 |
| 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 | [BR7C4L] |
| 5.b | Sample ID | [BS2X7C] |
| 5.c | Sample ID | [BS2X7D] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/28/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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/28/2021 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/28/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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 Date of Collection: Jan/28/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BR6GS4] |
| 5.b | Sample ID | [BSD79J] |
| 5.c | Sample ID | [BSD79K] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

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

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

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

Subject No: 12411269 **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: 12411269 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 : | Oct/8/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

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

Subject No: 12411269 **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 Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

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

Subject No: 12411269 **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 | [] |
|----|-----------|-----|

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Adverse Event Report

| | | |
|----|---|-----|
| 1. | Category: | |
| 2. | AE ID: | [] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [] |
| 4. | Start Date Time: | // |
| 5. | Is the adverse event still ongoing? | |
| 6. | Toxicity Grade: | |
| 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). | |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-----|---|-----|
| 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. | |
| 9. | Is this event related to study treatment: | |
| 10. | Latest Action Taken with Study Treatment: | |
| 11. | Was a Concomitant Medication given? | |
| 12. | Was a Non-Drug Treatment given? | |
| 13. | What was the outcome of this adverse event?: | |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae3f4f\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: 12411269

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. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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: For Pfizer Use Only | [] |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

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: 12411269

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. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: 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: | // |

090177e196ae3f4f\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: 12411269

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. | | | | | | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: 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? | |

090177e196ae3f4f\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: 12411269

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. | | | | | | Repeating Pages |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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? | |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

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: 12411269

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 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: 12411269

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: 12411269

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? | |

090177e196ae3f4f\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: 12411269

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: 12411269

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

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 12411269 **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/21/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 12411269 **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 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

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: 12411269

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/21/2021 |
| 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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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: V101_VAX3

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: 12411269

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/28/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Jan/28/2021 |
|----|--------------|--|

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

| | | |
|----|--|--------------------|
| 1. | Date of Completion/Discontinuation/Death : | Jan/28/2021 |
| 2. | Phase of Disposition: | REPEAT SCREENING 1 |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: V101_VAX3

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: 12411269

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? | NO |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [Sample is on Conv B1 visit] |

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 12411269

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 Date of Collection: Jan/28/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BR6GRM] |
|-----|-----------|----------|

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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 | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Jan/28/2021 11:15 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 12411269

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 | Feb/18/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 Date of Collection: Feb/18/2021 |
| 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 | [BRKFBK] |
|-----|-----------|----------|

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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 | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Feb/18/2021 10:32 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

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: 12411269

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411269

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

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: 12411269

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Oct/8/2020 |

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: 12411269

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: 12411269

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 | Feb-24-2021 15:00:10 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

Affidavit:

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

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

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|------------------|----------------|
| Form | Jan-28-2021 14:20:08 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1241

Site Name: (1241) Hospite Irma Dulce

Subject No: 12411269

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 | Feb-24-2021 15:00:10 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

Affidavit:

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

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

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Feb-18-2021 11:21:16 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|------------------|----------|--|------|--------|
| Edson Moreira | Approved | Feb-02-2021 13:36:38 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|------------------|----------|--|------|--------|

090177e196ae3f4f\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) Hospite Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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-28-2021 14:18:10 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|------------------|----------|--|------|--------|
| Edson Moreira | Approved | Jan-21-2021 17:29:42 (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.

090177e196ae3f4f\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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Jan-08-2021 15:37:02 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------|----------|--|------|--------|
| (b) (6) | Approved | Nov-25-2020 15:36:47 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|---------|----------|--|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Nov-20-2020 09:33:15 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|------------------|----------|--|------|--------|
| Edson Moreira | Approved | Oct-29-2020 16:38:54 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|------------------|----------|--|------|--------|

090177e196ae3f4f\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) Hospite Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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 | Oct-28-2020 10:59:54 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|------------------|----------|--|------|--------|
| Edson Moreira | Approved | Oct-26-2020 20:30:01 (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.

090177e196ae3f4f\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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Oct-26-2020 08:43:34 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|------------------|----------|--|------|--------|
| Edson Moreira | Approved | Oct-22-2020 23:29:35 (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.

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:16:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 30 JUN 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Aug-19-2020 15:16:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Consent Was:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:17:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Con- sent Obtained Aug/19/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------|--------------------------------------|
| Aug-19-2020 15:16:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12411269 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|------------------------------------|---------------------|
| Aug-19-2020 15:16:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6) 1977 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-19-2020 15:17:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: MALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:17:56 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATINO(A) OR OF | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

of Buenos Aires

SPANISH ORIGIN

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:17:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLACK OR AFRIC AN AMERICAN | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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 |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:18:05 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 1 usio n N um ber: Crit Male or female erio participants bet n D ween the ages escr of 18 and 55 ye ipti ars, inclusive, 6 on: 5 and 85 years, inclusive, or 18 and 85 years, i nclusive, at ran domization (de pendent upon s tudy stage) Crit YES erio n m et?: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|--|--|
| | | | Crit IN01A00 erion I D: (For Pfizer er use only) : | |
|--|--|--|--|--|

1.a Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

1.a Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

1.a Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN01A00 | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 2 usio n N umb er: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|--|--|
| | | | <p>Crit Participants w erio ho are willing n De and able to co scri mply with all s ptio cheduled visits n: , vaccination pl an, laboratory t ests, lifestyle c onsiderations, and other study procedures</p> <p>Crit YES erio n m et?:</p> <p>Crit IN02A00 erio n ID : (Fo r Pfi zer use only):</p> | |
|--|--|--|--|--|

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

1.b Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

1.b Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participants who are willing and able to co mply with all schedul ed visits, vaccination plan, laboratory tests, lifestyle consideratio ns, and other study pr ocedures | Initial Entry |

1.b Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN02A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

I.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 3 usio n N umb er: Crit Healthy partici erio pants who are n De determined by scri medical history ptio , physical exa n: mination, and c linical judge nt of the invest igator to be eli gible for inclus ion in the study Crit YES erio n m et?: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|---|--|
| | | | Crit IN03A00 erio n ID : (F or P fizer use only): | |
|--|--|--|---|--|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

1.c Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

1.c Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Healthy participants who are determined b y medical history, ph ysical examination, a nd clinical judgment of the investigator to be eligible for inclusi on in the study | Initial Entry |

1.c Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN03A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

1.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Incl 4 usio n N umb er: Crit Capable of giv erio ing personal si n De gned informed scri consent, which ptio includes compl n: iance with the requirements a nd restrictions listed in the IC D and in this p rotocol Crit YES erio n m et?: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

1.d Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 4 | Initial Entry |

1.d Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Capable of giving per sonal signed informe d consent, which incl udes compliance with the requirements and restrictions listed in t he ICD and in this pr otocol | Initial Entry |

1.d Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN04A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 1 usio n N umb er: Crit Other medical erio or psychiatric c n De ondition incl. r scri ecent (within p ptio ast year) or acti n: ve suicidal idea tion/behavior/l ab abnormality that may increa se the risk of st udy participati on Crit NO erio n m et?: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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|--|--|--|--|--|
| | | | Crit EX01A00 erion ID : (F or P fizer use only): | |
|--|--|--|--|--|

2.a Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Other medical or psy chiatric condition incl . recent (within past y ear) or active suicidal ideation/behavior/lab abnormality that may increase the risk of st udy participation | Initial Entry |

2.a Criterion met?

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX01A00 | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 2 usion Num ber: Crite Known infecti rion on with huma Desc n immunodefi riptio ciency virus (n: HIV), hepatiti s C virus (HC V), or hepatiti s B virus (HB V) | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

| | | | | |
|--|--|--|--|--|
| | | | Crite NO rion met? : Crite EX02A00 rion I D: (F or Pfi zer u se onl y): | |
|--|--|--|--|--|

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.b Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

2.b Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) | Initial Entry |

2.b Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX02A00 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City
of Buenos Aires

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

2.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 3 usio n N umb er: Crit History of severe erio re adverse reac n De tion associated scri with a vaccine ptio and/or severe a n: llergic reaction (eg, anaphylax is) to any com ponent of the s tudy interventi on(s) Crit NO erio n m et?: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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|--|--|--|--|--|
| | | | Crit EX03A00 erion ID : (For Pfizer use only): | |
|--|--|--|--|--|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.c Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

2.c Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: History of severe adverse reaction associated with a vaccine and /or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention (s) | Initial Entry |

2.c Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX03A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

2.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medication is intended to prevent COVID-19 Criterion met?: NO Criterion ID: (Formerly): EX04A00 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.d Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 4 | Initial Entry |

2.d Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Receipt of medication s intended to prevent COVID-19 | Initial Entry |

2.d Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX04A00 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 8 usio n Nu mbe r: Crit Immunocompr erio omised individ n De uals with kno scrip wn or suspecte tion: d immunodef ciency, as dete rmined by hist ory and/or lab oratory/physic al examination Crit NO erio n me t?: Crit EX08A00 erio n ID : (Fo r Pfi zer u se on ly): | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.e Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 8 | Initial Entry |

2.e Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Immunocompromised individuals with kno wn or suspected imm unodeficiency, as dete rmined by history and /or laboratory/physica l examination | Initial Entry |

2.e Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

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Header Text: c4591001

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Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX08A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

2.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 10 usio n Nu mbe r: Crit Bleeding diath erio esis or conditio n De n associated wi scri th prolonged bl ptio eeding that wo n: uld, in the opin ion of the inve stigator, contra indicate intram uscular injecti on Crit NO erio n me t?: | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|--|--|
| | | | Crit EX10A00 erion ID : (For Pfizer use only): | |
|--|--|--|--|--|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.f Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 10 | Initial Entry |

2.f Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bleeding diathesis or condition associated with prolonged bleedi ng that would, in the opinion of the investi gator, contraindicate i ntramuscular injectio n | Initial Entry |

2.f Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX10A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

2.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusio 11 n Numb er: Criteria Women w n Descri ho are pre ption: gnant or b reastfeedi ng Criteria NO n met?: Criteria EX11A00 n ID: (F or Pfizer use only) : | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.g Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 11 | Initial Entry |

2.g Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Women who are preg nant or breastfeeding | Initial Entry |

2.g Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX11A00 | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: (For Pfizer use only): EX12A00 | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.h Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 12 | Initial Entry |

2.h Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Previous vaccination with any coronavirus vaccine | Initial Entry |

2.h Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX12A00 | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 13 Criteria: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criteria met?: NO Criteria ID: EX13A01 For Pfizer use only: | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.i Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 13 | Initial Entry |

2.i Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Subjects who receive immunosuppressive t herapy, such as cyto xic agents or systemi c corticosteroids | Initial Entry |

2.i Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX13A01 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

of Buenos Aires

2.j

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 15 usio n Nu mbe r: Crit Receipt of blo erio od/plasma pro n De ducts or immu scrip noglobulin, fro tion: m 60 days bef ore study inter vention admini stration or plan ned receipt thr oughout the st udy Crit NO erio n me t?: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|--|--|
| | | | <p>Crit EX14A01 erio n ID : (Fo r Pfi zer use only):</p> | |
|--|--|--|--|--|

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.j Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 15 | Initial Entry |

2.j Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study | Initial Entry |

2.j Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX14A01 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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2.k

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 16 usio n Nu mbe r: Crite Participation i tion n other studie Desc s involving st ripti udy interventi on: on within 28 days prior to s tudy entry and /or during stu dy participati on Crite NO tion met? : Crite EX15A01 tion ID: (For Pfize r use only) : | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.k Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 16 | Initial Entry |

2.k Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participation in other studies involving stu dy intervention withi n 28 days prior to stu dy entry and/or durin g study participation | Initial Entry |

2.k Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX15A01 | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

2.1

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: NO Criterion ID: (For Pfizer use only): EX16A01 | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.1 Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 17 | Initial Entry |

2.1 Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Previous participatio n in other studies inv olving study interven tion containing lipid nanoparticles | Initial Entry |

2.1 Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.1 Criterion ID: (For Pfizer use only)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX16A01 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

2.m

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl 22 usio n N um ber: Crit Investigator sit erio e staff or Pfize n D r employees di escr rectly involved ipti in the conduct on: of the study, sit e staff otherwi se supervised b y the investigat or, and their re spective famil y members Crit NO erio n m et?: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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| | | | | |
|--|--|--|--|--|
| | | | Crit EX21A01 erion ID : (F or P fize r us e on ly): | |
|--|--|--|--|--|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.m Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 22 | Initial Entry |

2.m Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Investigator site staff or Pfizer employees directly involved in t he conduct of the stu dy, site staff otherwis e supervised by the i nvestigator, and their respective family me mbers | Initial Entry |

2.m Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-19-2020 15:18:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX21A01 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-19-2020 15:18:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-19-2020 15:18:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------------|---------------|
| Aug-19-2020 15:18:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Aug-19-2020 15:20:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH 1 Number: Medical H Vasectomy istory Ter m: Start Date UNK/UN : K/2016 Ongoing: NO End Date : UNK/U NK/201 6 | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:20:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

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

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|---------------------|---------------------------------|---------------|
| Aug-19-2020 15:20:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Vasectomy | Initial Entry |
|--|-----------------|---------------------|---------------------------------|---------------|

1.a Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------------|---------------|
| Aug-19-2020 15:20:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2016 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:20:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/2016 | Initial Entry |

090177e196ae3f4f\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: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 128.2 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------------|-----------------------------|---------------|
| Aug-19-2020 15:21:00 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 173.0 | Initial Entry |

090177e196ae3f4f\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: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

5. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|----------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 42.8 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location:: Y | Initial Entry |

090177e196ae3f4f\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: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.3 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-19-2020 15:21:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:21:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-19-2020 15:21:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 55770 | Initial Entry |

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 17:31:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Aug-19-2020 17:31:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Aug-19-2020 17:31:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-19-2020 17:31:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|---|-----------------------------|
| | | | | and correct as appropriate. |
| Aug-19-2020 17:31:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/19/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Aug-19-2020 17:31:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BP5S7 : X | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-19-2020 17:31:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP5S7X | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Aug-19-2020 17:31:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BP5S7 : Y | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-19-2020 17:31:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP5S7Y | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Aug-19-2020 17:32:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BP5S7 : Z | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-19-2020 17:32:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP5S7Z | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Aug-19-2020 17:32:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BLCHF : 0 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-19-2020 17:32:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLCHF0 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Aug-19-2020 17:32:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BLCHF : 1 | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-19-2020 17:32:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLCHF1 | Initial Entry |

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 17:32:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Aug-19-2020 17:32:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Aug-19-2020 17:33:05 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-19-2020 17:32:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|---|-----------------------------|
| | | | | and correct as appropriate. |
| Aug-19-2020 17:32:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/19/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Aug-19-2020 17:33:05 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP5S87 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-19-2020 17:33:05 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP5S87 | Initial Entry |

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 10:59 | Initial Entry |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

of Buenos Aires

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD | Initial Entry |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-19-2020 15:21:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3f4f\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: 12411269

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:22:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-09-2020 11:37:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Sep-09-2020 11:38:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-09-2020 11:38:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Temperature: 36.4 Temperature Unit: Temperature Location: ORAL CAVIT :: Y | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-09-2020 11:38:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

2.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-09-2020 11:38:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.4 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-09-2020 11:38:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-09-2020 11:38:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-09-2020 13:35:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-09-2020 13:35:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Sep-09-2020 13:35:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-09-2020 13:35:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|--|-----------------------------|
| | | | | and correct as appropriate. |
| Sep-09-2020 13:35:35 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/9/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-09-2020 13:35:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BPX0R : J | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-09-2020 13:35:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPX0RJ | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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 |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 10:42 | Initial Entry |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

of Buenos Aires

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD | Initial Entry |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-09-2020 11:39:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12411269 **Subject Initials:** ---

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020 13:46:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/8/2020 | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12411269 **Subject Initials:** ---

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-09-2020 12:19:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-09-2020 12:19:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Oct-09-2020 12:19:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-09-2020 12:19:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 12411269 Subject Initials: ---

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

| | | | | |
|---|-----------------|------------------|--|-----------------------------|
| | | | | and correct as appropriate. |
| Oct-09-2020 12:19:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/8/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-09-2020 12:19:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BPWXX D: M | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-09-2020 12:19:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPWXXM | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-09-2020 12:20:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BHJ01 : H | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12411269 **Subject Initials:** ---

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

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-09-2020 12:20:21 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BHJ01H | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 12:20:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BHJ01J | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-09-2020 12:20:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BHJ01J | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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 |
|---|-----------------|---------------------------|-------------------|---|
| Oct-28-2020 11:11:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Oct-28-2020 11:00:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | data updated |
| Oct-27-2020 09:08:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you. |
| Oct-26-2020 08:47:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-26-2020 08:44:43 (UTC-03:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|---------------------------|-----------------------------------|--|
| City of Buenos Aires | | | | |
| Oct-26-2020 08:43:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate. |
| Oct-26-2020 08:43:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Oct-26-2020 08:43:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/23/2020 | Initial Entry |

3. COVID-19 Illness Visit:

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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

| | | | | |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Oct-26-2020 08:43:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |
|--|-----------------|-------------------------|-------------------------------|---------------|

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/23/2020 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/17/2020 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|-----------------|
| Nov-20-2020 09:33:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: Oct/25/2020 | New Information |
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEV ER Symptom Present: YES | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

4.a Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR I NCREASE | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|-----------------|--|--|----------------------------|--|
| of Buenos Aires | | | D COUGH | |
| | | | Symptom Present: NO | |

4.b Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|---|--|
| | | | Symp YES tom Prese nt: | |
|--|--|--|---|--|

4.c Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREAS ED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHIL LS Symptom Pr NO esent: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.d Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sympt NEW OR IN oms: CREASED MUSCLE P AIN Sympt YES om Pr esent: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREAS ED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL Sympt YES om Pr esent: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.f Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW LOSS OF TAS TE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sympt NEW OR IN oms: CREASED S ORE THRO AT Sympt NO om Pr esent: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.g Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREAS ED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARR HEA Symptom YES Present: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.h Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMIT ING Symptom YES Present: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.i Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-26-2020 08:44:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:45:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - Asthe Other: nia | Initial Entry |

5.a Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-26-2020 08:45:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Asthenia | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:45:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - Other: Abdominal discomfort | Initial Entry |

5.b Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:45:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Abdominal discomfort | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:45:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - Other: Nausea | Initial Entry |

5.c Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-26-2020 08:45:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nausea | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Oct-28-2020 10:59:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-28-2020 10:59:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/24/2020 | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-28-2020 10:59:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWABBED MATERI AL | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-28-2020 10:59:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NASOPHARYNX | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Oct-28-2020 10:59:54 (UTC-03:00) City | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SEVERE ACUTE RES P SYNDROME CORO | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|-----------------|--|--|-----------|--|
| of Buenos Aires | | | NAVIRUS 2 | |
|-----------------|--|--|-----------|--|

5. Device Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Oct-28-2020 10:59:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SARS-COV-2 DIAGN OSTIC TEST | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-28-2020 10:59:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ROCHE MOLECUL AR SYSTEMS COB AS SARS-COV-2 | Initial Entry |

7. Test Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-28-2020 10:59:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-26-2020 08:47:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-26-2020 08:47:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Oct-26-2020 08:47:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-26-2020 08:47:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|---|-----------------------------|
| | | | | and correct as appropriate. |
| Oct-26-2020 08:47:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/23/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-26-2020 08:47:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I RW9287 D: 3 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Oct-26-2020 08:47:17 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RW92873 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - 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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-26-2020 08:47:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Oct-26-2020 08:47:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-26-2020 08:47:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Oct-26-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - 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

| | | | | |
|---|--|---------------------|----------------------------|--|
| 08:47:37 (UTC-03:00) City of Buenos Aires | | (b) (4), (b) (6) | Subject used self swa b | |
|---|--|---------------------|----------------------------|--|

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Prac SPEC itioner: IALI ST Occurrence o NO f Visits or Co ntacts: | Initial Entry |

1.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

1.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.b

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of EMERGE Practitio NCY RO ner: OM Occurre YES nce of Vi Number sits or C of Visits ontacts: or Conta cts: 1 | Initial Entry |

1.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROO M | Initial Entry |

1.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

1.c

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN Occurren NO ce of Visit s or Cont acts: | Initial Entry |

1.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE P HYSICIAN | Initial Entry |

1.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.d

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Oct-26-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|--|---------------------|---|--|
| 08:48:06 (UTC-03:00) City of Buenos Aires | | (b) (4), (b) (6) | Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | |
|---|--|---------------------|---|--|

1.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

1.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|-----------------|
| Nov-23-2020 13:55:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPH ONE CONSULTATION | New Information |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 10-Oct-2020 15:59

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - 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

| | | | | |
|--|-----------------|---------------------|--|---------------|
| | | | Occurrence of Visits or Contacts: NO | |
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

1.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: TELEPHONE CONS ULTATION | Initial Entry |

1.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|-----------------|
| Nov-23-2020 13:55:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | New Information |
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

1.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OT HE R | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|--|--|
| | | | Occurrence of NO Visits or Conta cts: | |
|--|--|--|--|--|

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-26-2020 08:48:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/23/2020

Form Version: 06-Jul-2020 21:52

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: ILLNESS DETAILS - 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

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Oct-26-2020 08:48:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: POTENTIAL COVID- 19 ILLNESS | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-26-2020 08:48:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-26-2020 08:48:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|-------------------|---|
| Jan-15-2021 07:45:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Jan-14-2021 15:34:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | data updated |
| Jan-12-2021 09:27:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you. |
| Jan-08-2021 15:38:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-08-2021 15:37:38 (UTC-03:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|---------------------------|----------------------------------|--|
| City of Buenos Aires | | | | |
| Jan-08-2021 15:37:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate. |
| Jan-08-2021 15:37:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Jan-08-2021 15:37:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 | Initial Entry |

3. COVID-19 Illness Visit:

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

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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

| | | | | |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Jan-08-2021 15:37:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_B | Initial Entry |
|--|-----------------|-------------------------|-------------------------------|---------------|

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/6/2021 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|-----------------|
| Jan-28-2021 14:18:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: Jan/9/2021 | New Information |
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEV ER Symptom Present: NO | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

4.a Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR I NCREASE | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|-----------------|--|--|----------------------------|--|
| of Buenos Aires | | | D COUGH | |
| | | | Symptom Present: NO | |

4.b Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|--|--|
| | | | Symp NO tom Prese nt: | |
|--|--|--|--|--|

4.c Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREAS ED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHIL LS Symptom Pr esent: YES | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.d Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sympt NEW OR IN oms: CREASED MUSCLE P AIN Sympt NO om Pr esent: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREAS ED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL Sympt NO om Pr esent: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.f Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW LOSS OF TAS TE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sympt NEW OR IN oms: CREASED S ORE THRO AT Sympt NO om Pr esent: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.g Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREAS ED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARR HEA Symptom YES Present: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.h Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMIT ING Symptom NO Present: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.i Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:37:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:37:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - Naus Other: ea | Initial Entry |

5.a Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 15:37:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nausea | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Jan-14-2021 15:34:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 06-Jul-2020 21:54

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - 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

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Jan-14-2021 15:34:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/9/2021 | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-14-2021 15:34:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWABBED MATERI AL | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-14-2021 15:34:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NASOPHARYNX | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Jan-14-2021 15:34:27 (UTC-03:00) City | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SEVERE ACUTE RES P SYNDROME CORO | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|-----------------|--|--|-----------|--|
| of Buenos Aires | | | NAVIRUS 2 | |
|-----------------|--|--|-----------|--|

5. Device Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Jan-14-2021 15:34:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SARS-COV-2 DIAGN OSTIC TEST | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-14-2021 15:34:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ROCHE MOLECUL AR SYSTEMS COB AS SARS-COV-2 | Initial Entry |

7. Test Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-14-2021 15:34:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-08-2021 15:38:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Jan-08-2021 15:38:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:38:09 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Jan-08-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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

15:38:09
(UTC-03:00) City
of Buenos Aires

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

Subject used site swa
b

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - 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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-08-2021 15:38:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-08-2021 15:38:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Jan-08-2021 15:38:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-08-2021 15:38:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|--|-----------------------------|
| | | | | and correct as appropriate. |
| Jan-08-2021 15:38:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/8/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-08-2021 15:38:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR798F | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-08-2021 15:38:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR798F | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form Version: 10-Dec-2020 02:26

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - 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

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1.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Prac SPEC itioner: IALI ST Occurrence o NO f Visits or Co ntacts: | Initial Entry |

1.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

1.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.b

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Pr EMER actioner: GENCY ROOM Occurrence NO of Visits or Contact s: | Initial Entry |

1.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROO M | Initial Entry |

1.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------------|---|---------------|
| Jan-08-2021 15:39:37 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of P PRIMAR | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|----------------------------------|--|------------------|---|--|
| (UTC-03:00) City of Buenos Aires | | (b) (4), (b) (6) | ractitioner: Y CARE PHYSICIAN Occurrence of Visits or Contacts: NO | |
|----------------------------------|--|------------------|---|--|

1.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

1.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.d

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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

1.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

1.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of P TELEPH ractitione ONE CO r: NSULTA TION Occurren NO ce of Visit s or Cont acts: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

1.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: TELEPHONE CONSULTATION | Initial Entry |

1.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

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 |
|--|-----------------|---------------------|-----------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:39:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/08/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Jan-08-2021 15:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: POTENTIAL COVID- 19 ILLNESS | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Jan-08-2021 15:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/20/2020

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-20-2020 09:33:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/20/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-20-2020 09:33:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_A1 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/20/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-20-2020 11:20:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-20-2020 11:20:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Nov-20-2020 11:20:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-20-2020 11:20:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/20/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|---|-----------------------------|
| | | | | and correct as appropriate. |
| Nov-20-2020 11:20:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Nov/20/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-20-2020 11:20:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BR7C4 : L | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Nov-20-2020 11:20:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR7C4L | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-20-2020 11:21:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BS2X7 : C | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/20/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-20-2020 11:21:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BS2X7C | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-20-2020 11:21:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BS2X7 : D | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-20-2020 11:21:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BS2X7D | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/28/2021

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411269

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-28-2021 14:18:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/28/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-28-2021 14:18:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_B1 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/28/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-28-2021 19:21:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-28-2021 19:21:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Jan-28-2021 19:21:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-28-2021 19:21:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/28/2021

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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|---------------------|---|-----------------------------|
| | | | | and correct as appropriate. |
| Jan-28-2021 19:21:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/28/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-28-2021 19:21:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BR6GS : 4 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-28-2021 19:21:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR6GS4 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-28-2021 19:21:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BSD79J | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Jan/28/2021

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411269

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

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-28-2021 19:21:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BSD79J | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-28-2021 19:22:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BSD79 : K | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-28-2021 19:22:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BSD79K | Initial Entry |

090177e196ae3f4f\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, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020 13:47:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/8/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-09-2020 13:47:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------|---------------|
| Oct-09-2020 13:47:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 12411269 **Subject Initials:** ---

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-28-2021 14:19:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/21/2021 | Initial Entry |

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

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

Subject No: 12411269 **Subject Initials:** ---

Generated By: (b) (4) **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-28-2021 14:19:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/n ational recommen dations and confir med to have receiv ed only placebo at Vaccination 1/2 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-28-2021 14:19:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/21/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-28-2021 14:19:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411269

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-28-2021 14:19:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/28/2021 | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-28-2021 14:19:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Jan/28/2021 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-28-2021 14:20:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/28/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Jan-28-2021 14:20:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------|---------------|
| Jan-28-2021 14:20:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-28-2021 14:24:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-28-2021 14:24:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-28-2021 14:24:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Jan-28-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|--|---------------------|--------------------------------|--|
| 14:24:56 (UTC-03:00) City of Buenos Aires | | (b) (4), (b) (6) | Sample is on Conv B 1 visit | |
|---|--|---------------------|--------------------------------|--|

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-28-2021 16:10:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-28-2021 16:10:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Jan-28-2021 16:10:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-28-2021 16:10:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|---|-----------------------------|
| | | | | and correct as appropriate. |
| Jan-28-2021 16:10:14 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/28/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-28-2021 16:10:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BR6GR D: M | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-28-2021 16:10:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR6GRM | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1241

Subject No: 12411269

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

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/28/2021 11:15 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

of Buenos Aires

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

9. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Jan-28-2021 14:20:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411269

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Feb-18-2021 11:21:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/18/2021 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-18-2021 12:07:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-18-2021 12:07:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|---|
| Feb-18-2021 12:08:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-18-2021 12:07:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|---|-----------------------------|
| | | | | and correct as appropriate. |
| Feb-18-2021 12:07:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/18/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-18-2021 12:08:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BRKFB D: K | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Feb-18-2021 12:08:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRKFBK | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1241

Subject No: 12411269

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

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/18/2021 10:32 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

of Buenos Aires

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

9. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Feb-18-2021 11:21:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3f4f\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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Oct-09-2020 13:47:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Aug-19-2020 15:21:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-19-2020 15:18:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-09-2020 13:47:13 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/8/2020 | Initial Entry |
| Aug-19-2020 15:21:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/19/2020 | Initial Entry |
| Aug-19-2020 | ACV0PFEINFP6000 | auto calc | Data Entry: | Initial Entry |

090177e196ae3f4f\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: 12411269

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|--|------------|-------------|--|
| 15:18:46 (UTC-03:00) City of Buenos Aires | | (autocalc) | Aug/19/2020 | |
|---|--|------------|-------------|--|

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411269

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Casebook Signature

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------------|--|---------------|
| Oct-22-2020 23:29:26 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Edson Moreira (b) (4) | Data Entry: Click Here to Enable | Initial Entry |

090177e196ae3f4f\Final\Final On: 01-Apr-2021 05:16 (GMT)