

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[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 |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: COHORT_SELECTION
Form Version: 22-Apr-2020 21:02
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: MAIN INFORMED CONSENT
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Sep/7/2020 |
|----|--------------|---|

Header Text: C4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY
Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

| Demography | | |
|------------|---------------------------------|--|
| 1. | Subject ID | [12261599] |
| 2. | Birth Date: | (b) (6)/1979 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

| | |
|--|--|
| Header Text: C4591001 | Form: DATE OF VISIT |
| Visit: V1_DAY1_VAX1_L | Form Status: Data Complete, Locked, Frozen, Verified |
| Form Version: 22-Apr-2020 21:02 | Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda |
| Site No: 1226 | Subject Initials: --- |
| Subject No: 12261599 | Generated Time (GMT): 29-Mar-2021 13:54 |
| Generated By: (b) (4) | |

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|------------|
| 1. | Date of Visit | Sep/7/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[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 |
| 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: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | |
|-----|-------------------------------------|--|
| 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 |
| 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 Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

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Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: DISPOSITION - SCREENING
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

| Disposition - Screening | | |
|-------------------------|---|------------|
| 1. | Date of Completion/Discontinuation /Death | Sep/7/2020 |
| 2. | Phase of Disposition: | SCREENING |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|---|-----------------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies: | [headache] |
| | Start Date: | UNK/UNK/2010 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies: | [Albright's osteodystrophy] |
| | Start Date: | UNK/UNK/2017 |
| | Ongoing: | YES |

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Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:51
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|------------|
| 1. | Date: | Sep/7/2020 |
| 2. | Weight: | [71.3] |
| 3. | Unit: | kg |
| 4. | Height: | [160.9] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [27.5] |

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [36.7] |
| | Unit: | C |
| | Temperature Location: | FOREHEAD |

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Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:49
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)
Form: LAB URINALYSIS - PREGNANCY TEST
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Sep/7/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: RANDOMIZATION
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

| Disposition | | |
|-------------|-----------------------|------------|
| 1. | Randomization Date : | Sep/7/2020 |
| 2. | Randomization Number: | [83114] |
| 3. | Randomization Group: | [] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Sep/7/2020 |
| 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 | [BPTJVP] |
| 5.b | Sample ID | [BPTJVR] |
| 5.c | Sample ID | [BPTJVS] |
| 5.d | Sample ID | [BPHNYH] |
| 5.e | Sample ID | [BPHNYJ] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/7/2020 |
| 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 | [BPTJVB] |
|-----|-----------|----------|

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:04
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)
Form: VACCINATION
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[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/7/2020 13:18 |
| 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 |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 06-Jul-2020 21:53
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: REACTOGENICITY DIARY
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V2_VAX2_L
Form Version: 15-Sep-2020 21:54
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: VITAL SIGNS - TEMP
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Oct/2/2020 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [36.5] |
| | Unit: | C |
| | Temperature Location: | FOREHEAD |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V2_VAX2_L
Form Version: 21-Aug-2020 02:49
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)
Form: LAB URINALYSIS - PREGNANCY TEST
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V2_VAX2_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V2_VAX2_L **Form:** VACCINATION
Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

| Vaccination | | |
|-------------|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Oct/2/2020 13:50 |
| 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 |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

| | |
|--|--|
| Header Text: C4591001 | Form: DATE OF VISIT |
| Visit: V3_MONTH1_POSTVAX2_L | Form Status: Data Complete, Locked, Frozen, Verified |
| Form Version: 22-Apr-2020 21:02 | Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda |
| Site No: 1226 | Subject Initials: --- |
| Subject No: 12261599 | Generated Time (GMT): 29-Mar-2021 13:54 |
| Generated By: (b) (4) | |

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|------------|
| 1. | Date of Visit | Nov/3/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001
Visit: V3_MONTH1_POSTVAX2_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)
Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BR78CT] |
| 5.b | Sample ID | [BS2VC9] |
| 5.c | Sample ID | [BS2VCB] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

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

Header Text: C4591001
Visit: V4_MONTH6_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Status: Not Started
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V5_MONTH12_L
Form Version: 22-Apr-2020 21:02
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: DATE OF VISIT
Form Status: Not Started
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001
Visit: V5_MONTH12_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Status: Not Started
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

| | |
|--|--|
| Header Text: C4591001 | Form: DATE OF VISIT |
| Visit: V6_MONTH24_L | Form Status: Not Started |
| Form Version: 22-Apr-2020 21:02 | Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda |
| Site No: 1226 | Subject Initials: --- |
| Subject No: 12261599 | Generated Time (GMT): 29-Mar-2021 13:54 |
| Generated By: (b) (4) | |

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

Header Text: C4591001
Visit: V6_MONTH24_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Status: Not Started
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

| Date of Visit | | |
|------------------------|-------------------------|------------|
| 1. | Date of Visit | Nov/7/2020 |
| 2. | Erroneous Visit | |
| COVID-19 Illness Visit | | |
| 3. | COVID-19 Illness Visit: | COVID_A |

Header Text: C4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Not Complete
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Signs and Symptoms

| | | |
|----|--------------------------------|---|
| 1. | Date of Assessment: | Nov/7/2020 |
| 2. | Date of First Symptom Started: | Nov/6/2020 |
| 3. | Symptoms Ongoing? | NO Date of Last Symptom Resolved: Nov/13/2020 |

Symptoms

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

Symptoms - Other

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|------------------|------------------------------|--|----------------------------|---------------------------------|
| 1. | Nov/7/2020 | SWABBED MATERIAL | NASOPHARYNX | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[Form Audit Trail](#)

Microbiology Specimen

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | YES Date of Collection: Nov/11/2020 |
| 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 | [RW91559] |
|-----|-----------|-----------|

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Nov/7/2020 |
| 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 | [BR6946] |
|-----|-----------|----------|

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020
Form: HEALTH CARE UTILIZATION
Form Version: 10-Oct-2020 15:59
Form Status: Data Complete, Frozen, Verified
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| # | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Treatment | Start Date | Form Instance |
|----|----------------------|---------------------------------------|----------------|----------------|----------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Respiratory Treatment

| | | | |
|----|--|--------------------------------|--------------------------|
| 1. | What is the treatment Identifier? | Not Applicable _____ [] | Comments |
| 2. | Concomitant Non-drug Treatment Pre-specified: | Not Applicable _____ | Comments |
| 3. | Treatment: | Not Applicable _____ | Comments |
| 4. | Treatment: | Not Applicable _____ [] | Comments |
| 5. | Start Date: | Not Applicable _____ // | Comments |
| 6. | Ongoing? | Not Applicable _____ | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020
Form: ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52
Form Status: Data Complete, Frozen, Verified
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

| Illness Details | | |
|-----------------|--|---|
| 1. | Category of Clinical Event: | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | YES Respiratory Illness Diagnosis: [COVID-19] Date of Diagnosis: Nov/7/2020 |
| 3. | Toxicity Grade: | 2 |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

| # | Category of Clinical Event: | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance |
|----|-----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Illness Details

| | | | |
|----|--------------------------------|----------------|--------------------------|
| 1. | Category of Clinical Event: | Not Applicable | Comments |
| 2. | Subcategory of Clinical Event: | Not Applicable | Comments |
| 3. | Was a diagnosis obtained? | Not Applicable | Comments |
| 4. | Toxicity Grade: | Not Applicable | Comments |

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|----------------|------------------|----------------|-----------------------------------|----------------|----------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Lab Chemistry Details

| | | | |
|----|-----------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Laboratory Name and Address | Not Applicable _____ [] | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 5.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | C Reactive Protein_PX329 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|-----|-------------|--|--------------------------|
| 5.b | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Alanine Aminotransferase_PX30 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |
| 5.c | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Aspartate Aminotransferase_PX28 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Alkaline Phosphatase_PX35 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |
| 5.e | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Bilirubin_PX21 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Blood Urea Nitrogen_PX47 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |
| 5.g | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Creatinine_PX48 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| # | Category for Lab Test | Vendor Name (DE RIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|------------------------|------------------|----------------|----------------------------|----------------|----------------|---------------------------------|
| | | | | | Sponsor-Defined Identifier | Test: | Result: | |
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[eCRF Audit Trail History](#)

Laboratory Data Hematology

| | | | |
|----|-----------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Laboratory Name and Address | Not Applicable _____ [] | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 5.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Hemoglobin_PX1 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|-----|-------------|--|--------------------------|
| 5.b | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Hematocrit_PX2 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

| | | | |
|-----|-------------|--|--------------------------|
| 5.c | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Erythrocytes_PX3 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Platelets_PX5 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |
| 5.e | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Leukocytes_PX7 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Neutrophils_PX608 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |
| 5.g | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Eosinophils_PX609 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|-----|-------------|--|--------------------------|
| 5.h | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Monocytes_PX612 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |
| 5.i | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Basophils_PX610 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|-----|-------------|--|--------------------------|
| 5.j | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Lymphocytes_PX611 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| # | Date: | Vital Signs Details | | | Form Instance |
|----|------------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Nov/7/2020 | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |
| | | 1 | 133 | 92 | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Nov/7/2020 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|---|-------|
| 2.a | Record Identifier: | 1 |
| | Systolic: | [133] |
| | Diastolic: | [92] |
| | Respiratory Rate in respirations/minute: | [16] |
| | Heart Rate in beats/minute: | [89] |

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| # | Date: | Vital Signs Details | | Form Instance | | | | |
|--------------------|-------------------|--|--------------------|-------------------|---|------|--|---------------------------------|
| 1. | Nov/7/2020 | <table border="1"><thead><tr><th>Record Identifier:</th><th>Oxygen Saturation</th></tr></thead><tbody><tr><td>1</td><td>93.0</td></tr></tbody></table> | Record Identifier: | Oxygen Saturation | 1 | 93.0 | | Repeating Pages |
| Record Identifier: | Oxygen Saturation | | | | | | | |
| 1 | 93.0 | | | | | | | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Nov/7/2020 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|--------|
| 2.a | Record Identifier: | 1 |
| | SPO2 Pulse Oximetry % | [93.0] |

Header Text: C4591001
Visit: POT_COVID_ILL 1 **Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

| # | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Oxygenation Parameters

| | | | |
|----|------------------------------------|--------------------------------|--------------------------|
| 1. | Date Time of Assessment: | Not Applicable _____ // | Comments |
| 2. | Arterial Blood Gases PaO2 (mmHg): | Not Applicable _____ [] | Comments |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | Not Applicable _____ [] | Comments |

Header Text: C4591001
Visit: POT_COVID_ILL 1
Form Version: 06-Jul-2020 21:55
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)
Form: CONCOMITANT MEDICATIONS - VASOPRESSORS
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|----------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Start Date: | Not Applicable _____ // | Comments |
| 6. | Ongoing? | Not Applicable _____ | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 **Form:** IMAGING
Form Version: 06-Jul-2020 21:53
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

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Imaging

| | | | |
|----|-------------------------|-------------------------------|--------------------------|
| 1. | Date of Assessment: | Not Applicable _____ // | Comments |
| 2. | Location of Assessment: | Not Applicable _____ | Comments |
| 3. | Type of Imaging Exam: | Not Applicable _____ | Comments |
| 4. | Assessment: | Not Applicable _____ | Comments |

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Feb/06/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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| Date of Visit | | |
|------------------------|-------------------------|------------|
| 1. | Date of Visit | Feb/6/2021 |
| 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 Feb/06/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261599**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[eCRF Audit Trail History](#)**Signs and Symptoms**

| | | |
|----|--------------------------------|------------|
| 1. | Date of Assessment: | Feb/6/2021 |
| 2. | Date of First Symptom Started: | Feb/4/2021 |
| 3. | Symptoms Ongoing? | YES |

Symptoms

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

Symptoms - Other

| | | |
|-----|------------------------|--------------|
| 5.a | Symptoms - Other Text: | [Runny nose] |
|-----|------------------------|--------------|

Header Text: C4591001
Visit: POT_COVID_ILL 2 **Form:** MICROBIOLOGY SPECIMEN
Form Version: 06-Jul-2020 21:54
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|----------------|------------------------------|----------------------------|----------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Microbiology Specimen

| | | | |
|----|-------------------------------|--------------------------------|--------------------------|
| 1. | Actual Date of Collection: | Not Applicable _____ // | Comments |
| 2. | Specimen Type: | Not Applicable _____ | Comments |
| 3. | Specimen Collection Location: | Not Applicable _____ | Comments |
| 4. | Assay Code and Description: | Not Applicable _____ | Comments |
| 5. | Device Type: | Not Applicable _____ | Comments |
| 6. | Trade Name: | Not Applicable _____ | Comments |
| 7. | Test Result: | Not Applicable _____ | Comments |
| 8. | Comments/Findings/Details: | Not Applicable _____ [] | Comments |
| 9. | Trade Name Other, Specify: | Not Applicable _____ [] | Comments |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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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: | [Collected on site, recorded at SWAB PFE] |

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Feb/6/2021 |
| 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 | [BRH04K] |
|-----|-----------|----------|

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261599**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: C4591001
Visit: POT_COVID_ILL 2 **Form:** RESPIRATORY TREATMENT
Form Version: 06-Jul-2020 21:53
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Respiratory Treatment

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

Header Text: C4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021
Form: ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52
Form Status: Data Complete
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

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| Illness Details | | |
|-----------------|--|----------------------------|
| 1. | Category of Clinical Event: | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | NO |
| 3. | Toxicity Grade: | 1 |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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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: 21-Aug-2020 02:49

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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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 |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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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 |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 2 **Form:** VITAL SIGNS - COVID
Form Version: 21-Aug-2020 02:50
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

| # | Date: | Vital Signs Details | | | Form Instance |
|----|------------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Feb/6/2021 | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |
| | | 1 | 139 | 93 | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Feb/06/2021

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Feb/6/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|---|-------|
| 2.a | Record Identifier: | 1 |
| | Systolic: | [139] |
| | Diastolic: | [93] |
| | Respiratory Rate in respirations/minute: | [16] |
| | Heart Rate in beats/minute: | [78] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| # | Date: | Vital Signs Details | | Form Instance |
|----|------------|---------------------------|--------------------------|---------------------------------|
| 1. | Feb/6/2021 | Record Identifier: | Oxygen Saturation | Repeating Pages |
| | | 1 | 99.0 | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Feb/6/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|--------|
| 2.a | Record Identifier: | 1 |
| | SPO2 Pulse Oximetry % | [99.0] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: OXYGENATION PARAMETERS

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Status: Not Started

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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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? | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 2 **Form:** IMAGING
Form Version: 06-Jul-2020 21:53
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | | | | | Repeating Pages |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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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 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Dec/15/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

| Date of Visit | | |
|------------------------|-------------------------|-------------|
| 1. | Date of Visit | Dec/15/2020 |
| 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 Dec/15/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Dec/15/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BRGTHM] |
| 5.b | Sample ID | [BSF217] |
| 5.c | Sample ID | [BSF21D] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/08/2020 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Sep/8/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001
Visit: Unplanned 1 - Unscheduled Visit on Sep/08/2020 **Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Unplanned Assessments

| | | |
|----|-------------|-----------------|
| 1. | Assessments | CONTACT OUTCOME |
|----|-------------|-----------------|

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Unplanned 1 - Unscheduled Visit on Sep/08/2020 **Form:** CONTACT OUTCOME - UNPLANNED
Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

| Contact Outcome | | |
|-----------------|-------------------|--|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Sep/8/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION |
| 3. | Comments: | [Contact made due to covid-19 symptom alert. Patient refers muscle pain on 07Sep2020 (grade1), related to vaccine reactogenicity.] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition - Treatment

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

| | |
|--|--|
| Header Text: C4591001 | Form: DISPOSITION - FOLLOW-UP |
| Visit: Follow-Up - Unscheduled | Form Status: Not Started |
| Form Version: 15-Sep-2020 21:53 | Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda |
| Site No: 1226 | Subject Initials: --- |
| Subject No: 12261599 | Generated Time (GMT): 29-Mar-2021 13:54 |
| Generated By: (b) (4) | |

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

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

Header Text: C4591001
Visit: Unplanned Vaccination - Unscheduled **Form:** VITAL SIGNS - TEMP
Form Version: 28-Mar-2021 02:28 **Form Status:** Not Started
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

Vital Signs

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

Vital Signs Details

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Unplanned Vaccination - Unscheduled **Form:** LAB URINALYSIS - PREGNANCY TEST
Form Version: 20-Feb-2021 02:14 **Form Status:** Not Started
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Unplanned Vaccination - Unscheduled **Form:** VACCINATION
Form Version: 10-Dec-2020 02:26 **Form Status:** Not Started
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

| 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? | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Unplanned Vaccination - Unscheduled
Form Version: 10-Oct-2020 15:57
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 1
Form Status: Not Started
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Unplanned Vaccination - Unscheduled
Form Version: 10-Oct-2020 16:01
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 6
Form Status: Not Started
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

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

Header Text: C4591001
Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29 **Form Status:** Not Started
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

| Informed Consent - Asymptomatic Surveillance | |
|--|--------------|
| 1. | Consent Was: |

Header Text: C4591001
Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Feb/5/2021 |
| 2. | Erroneous Visit | |

Header Text: C4591001
Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[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 and NOT confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|-------------------------|---------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | myalgia | Sep/7/2020 20:00 | NO End Date Time: Sep/10/2020 UNK:UNK | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | fatigue | Sep/7/2020 20:00 | NO End Date Time: Sep/10/2020 UNK:UNK | Repeating Pages |
| 3. | ADVERSE EVENT | 3 | corneal ulcer right eye | Sep/20/2020 UNK:UNK | NO End Date Time: Sep/27/2020 UNK:UNK | Repeating Pages |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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[Form Audit Trail](#)

Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [myalgia] |
| 4. | Start Date Time: | Sep/7/2020 20:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/10/2020 UNK:UNK |
| 6. | Toxicity Grade: | 1 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [fatigue] |
| 4. | Start Date Time: | Sep/7/2020 20:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/10/2020 UNK:UNK |
| 6. | Toxicity Grade: | 1 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Adverse Event Report

| | | |
|-----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [3] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [corneal ulcer right eye] |
| 4. | Start Date Time: | Sep/20/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/27/2020 UNK:UNK |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [prolonged use of contact lens] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Locked, Frozen
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

| | | |
|-----|--|-----|
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Logs **Form:** MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Medication Error

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Concomitant Medications

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Concomitant Medications

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Logs **Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Radiation Treatment

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: Logs **Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: TRANSFUSIONS
Form Status: Not Started
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

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

Header Text: C4591001
Visit: UNPLANNED_BOOSTER_CONTACT - Unscheduled
Form: BOOSTER DOSE TRIGGER FORM
Form Version: 20-Feb-2021 02:20
Form Status: Not Started
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

| Booster Dose Trigger Form | |
|---------------------------|--|
| 1. | Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit? |

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Feb/5/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

| | |
|---|--|
| Header Text: C4591001 | Form: WITHDRAWAL OF CONSENT |
| Visit: Disposition - Unscheduled | Form Status: Not Started |
| Form Version: 22-Apr-2020 21:03 | Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda |
| Site No: 1226 | Subject Initials: --- |
| Subject No: 12261599 | Generated Time (GMT): 29-Mar-2021 13:54 |
| Generated By: (b) (4) | |

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

Header Text: C4591001
Visit: Disposition - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: DEATH DETAILS CODED
Form Status: Not Started
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

Death Details

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

Cause of Death

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Nov/3/2020 |

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-------------------|-------------------|---|------|--------|
| Cristiano Zerbini | Approved | Feb-11-2021 17:33:50 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

Affidavit:

By my dated signature below, I, CristianoZerbini, 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.

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | |
| Form | Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
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| 1 | Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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Header Text: C4591001

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Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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Header Text: C4591001

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| 9 | Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

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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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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Generated By: (b) (4)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-------------------|-------------------|---|------|--------|
| Cristiano Zerbini | Approved | Feb-11-2021 17:33:50 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-08-2021 08:24:08 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-------------------|----------|---|------|--------|
| Cristiano Zerbini | Approved | Jan-21-2021 16:50:53 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|-------------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, CristianoZerbini, 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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| (b) (6) | N/A | Dec-15-2020 16:46:07 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
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Affidavit:

N/A

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| Cristiano Zerbini | Approved | Nov-16-2020 09:29:09 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
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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:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261599**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54**Affidavit:**

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| (b) (6) | N/A | Nov-16-2020 08:00:34 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
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Affidavit:

N/A

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| Cristiano Zerbini | Approved | Nov-15-2020 09:47:47 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
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| (b) (6) | N/A | Nov-13-2020 15:30:55 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
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Affidavit:

N/A

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| Cristiano Zerbini | Approved | Nov-11-2020 21:53:20 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
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| (b) (6) | N/A | Nov-07-2020 12:51:41 (UTC-03:00) City of Buenos Aires | | Edit - All signatures invalidated |
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Affidavit:

N/A

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

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Generated By: (b) (4)

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Form Status: Data Complete, Signed, Verified

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| | | | | |
|-------------------|----------|---|------|--------|
| Cristiano Zerbini | Approved | Nov-06-2020 15:39:20 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|-------------------|----------|---|------|--------|

Affidavit:

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

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-07-2020 15:42:12 (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 |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Sep-07-2020 15:42:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: COHORT_SELECTION
Form Version: 22-Apr-2020 21:02
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

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I. Consent Was:

| Date | Location | User | Value | Reason |
|--|-----------------|---|---|---------------|
| Sep-07-2020 15:42:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: OBTAINED Date Written Consent Obtained Sep/7/2020 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Subject ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------|--------------------------------|
| Sep-07-2020 15:42:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12261599 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|------------------|
| Sep-07-2020 15:42:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6) /1979 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-07-2020 15:42:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:42:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Sep-07-2020 15:42:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-07-2020 15:42:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/7/2020 | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

I.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Inclusion Number: Criteria on 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) Criteria on met?: Criteria on ID: (For Pfizer use only): IN01A00 | Initial Entry |

I.a Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

I.a Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (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 |

I.a Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN01A00 | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Inclusion Number: 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 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

1.b Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures | Initial Entry |

1.b Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN02A00 | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Inclusion Number: 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 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|--|--|
| | | | Criterion ID: (For Pfizer use only): IN03A00 | |
|--|--|--|--|--|

I.c Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

I.c Criterion Description:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study | Initial Entry |

I.c Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN03A00 | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Inclusion Number: | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|---|--|
| | | | <p>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</p> <p>Criterion met?: YES</p> <p>Criterion ID: (For Pfizer use only): IN04A00</p> | |
|--|--|--|---|--|

1.d Inclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol | Initial Entry |

1.d Criterion met?:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: IN04A00 | Initial Entry |

2.a

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 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?: Criterion ID: (For Pfizer use only): EX01A00 | Initial Entry |
|--|-----------------|---------------------|--|---------------|

2.a Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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 | Initial Entry |

2.a Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX01A00 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

2.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion 2 Number: Criterion Known infection with human Descriptio immunodeficiency virus (HIV n:), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion NO met?: Criterion EX02A00 ID: (For Pfizer use only): | Initial Entry |

2.b Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX02A00 | Initial Entry |

2.c

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusio 3 n Numb er: Criteria History of severe adverse reacti n Descri on associated with a vaccine an ption: d/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) Criteria NO n met?: Criteria EX03A00 n ID: (F or Pfize r use on ly): | Initial Entry |

2.c Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: History of severe adverse reaction associat ed with a vaccine and/or severe allergic re action (eg, anaphylaxis) to any component of the study intervention(s) | Initial Entry |

2.c Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX03A00 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

2.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Num 4 ber: Criterion Descr Receipt of medications intended to prevent CO iption: VID-19 Criterion met?: NO Criterion ID: (EX04A00 For Pfizer use o nly): | Initial Entry |

2.d Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Receipt of medications intended to prevent COVID-19 | Initial Entry |

2.d Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX04A00 | Initial Entry |

2.e

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: Criterion Description: Criterion met?: Criterion ID: (For Pfizer use only): | Initial Entry |
|--|-----------------|---------------------|--|---------------|

2.e Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination | Initial Entry |

2.e Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX08A00 | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

2.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

2.f Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection | Initial Entry |

2.f Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX10A00 | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (For Pfizer use only): EX11A00 | Initial Entry |

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Header Text: C4591001

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Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Subject Initials: ---

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2.g Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Women who are pregnant or breastfeeding | Initial Entry |

2.g Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX11A00 | Initial Entry |

2.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: (For Pfizer use only): EX12A00 | Initial Entry |

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Header Text: C4591001

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Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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2.h Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX12A00 | Initial Entry |

2.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion 13 Number: Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: NO Criterion I EX13A01 D: (For Pfizer use only): | Initial Entry |

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Generated By: (b) (4)

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2.i Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids | Initial Entry |

2.i Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX13A01 | Initial Entry |

2.j

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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 | Initial Entry |

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Header Text: C4591001

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Subject No: 12261599

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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| | | | | |
|--|--|--|--|--|
| | | | Criterion ID: (For Pfizer use only): EX14A01 | |
|--|--|--|--|--|

2.j Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX14A01 | Initial Entry |

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Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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| 2.k | | | | |
|--|-----------------|---------------------|---|---------------|
| Date | Location | User | Value | Reason |
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusio 16 n Numbe r: Criterion Participation in other studies i Descripti nvolving study intervention w on: ithin 28 days prior to study ent ry and/or during study particip ation Criterion NO met?: Criterion EX15A01 ID: (For Pfizer us e only): | Initial Entry |

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Header Text: C4591001

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Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

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2.k Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation | Initial Entry |

2.k Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX15A01 | Initial Entry |

2.l

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: 17 Criterion Description: Previous participation in other studies involving study in intervention containing lipid nanoparticles Criterion met?: NO Criterion ID (For Pfizer use only): EX16A01 | Initial Entry |

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Header Text: C4591001

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Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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2.1 Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles | Initial Entry |

2.1 Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX16A01 | Initial Entry |

2.m

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exclusion Number: Criteria on 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 Criteria on met?: NO | Initial Entry |

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Header Text: C4591001

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Subject No: 12261599

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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| | | | | |
|--|--|--|-----------------------------|--|
| | | | Criteria ID: EX21A01 | |
| | | | For Pfizer use only: | |

2.m Exclusion Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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 |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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 | Initial Entry |

2.m Criterion met?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:43:11 (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)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Sep-07-2020 15:43:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EX21A01 | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-07-2020 15:43:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/7/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-07-2020 15:43:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------|---------------|
| Sep-07-2020 15:43:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Sep-07-2020 15:45:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Term: headache Start Date: UNK/UNK/2010 Ongoing: YES | Initial Entry |

I.a Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-07-2020 15:45:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-07-2020 15:45:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: headache | Initial Entry |

I.a Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------------|---------------|
| Sep-07-2020 15:45:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2010 | Initial Entry |

I.a Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-07-2020 15:45:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|-----------------|
| Sep-11-2020 12:56:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number 2 : | New Information |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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| | | | | |
|--|-----------------|-------------------------|---|---------------|
| | | | Medical History Term: Albright's osteodystrophy Start Date: UNK/UNK/2017 Ongoing: YES | |
| Sep-07-2020 15:46:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 2 Medical History Term: hypothyroidism (Albright's osteodystrophy) Start Date: UNK/UNK/2017 Ongoing: YES | Initial Entry |

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Subject No: 12261599

Generated By: (b) (4)

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

1.b Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-07-2020 15:46:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|---|-----------------------------|--|--|
| Sep-12-2020 03:30:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Closed | Discrepancy has been closed. |
| Sep-11-2020 12:56:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Sep-11-2020 12:56:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Albright's osteodystrophy | New Information |
| Sep-07-2020 18:32:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Opened | Clarify HYPOTHYROIDISM (ALBRIGHT'S OSTEODYSTROPHY) as follows...Term is unclear. Are you reporting PSEUDOHYPOPARATHYROIDISM (ALBRIGHT'S OSTEODYSTROPHY)? Or PSEUDOPSEUDOHYPOPARATHYROIDISM (ALBRIGHT'S OSTEODYSTROPHY)? If so, update the verbatim term as such. If reporting HYPOTHYROIDISM and ALBRIGHT'S OSTEODYSTROPHY, split and report as 2 separate entries. Otherwise clarify and update the term as appropriate. Thank you. |
| Sep-07-2020 15:46:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : hypothyroidism (Albright's osteodys | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|--------|---|
| | | | trophy |) |
|--|--|--|--------|---|

I.b Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------------|---------------|
| Sep-07-2020 15:46:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2017 | Initial Entry |

I.b Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-07-2020 15:46:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sep/7/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 71.3 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 160.9 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 27.5 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

7.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Location:: FOREHEAD | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:47:28 (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 |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.7 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-07-2020 15:47:28 (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 |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-07-2020 15:47:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/7/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined I 113 dentifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done:: | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-07-2020 15:48:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEGATIVE | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-07-2020 15:50:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/7/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Sep-07-2020 15:50:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 83114 | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-08-2020 09:04:19 (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-08-2020 09:04:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|--|
| Sep-08-2020 09:04:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-08-2020 09:04:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-08-2020 09:04:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/7/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-08-2020 09:04:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPTJVP | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 09:04:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPTJVP | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-08-2020 09:04:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPTJVR | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 09:04:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPTJVR | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-08-2020 09:04:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPTJVS | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 09:04:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPTJVS | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-08-2020 09:04:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPHNYH | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 09:04:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPHNYH | Initial Entry |

5.e

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-08-2020 09:05:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPHNYJ | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 09:05:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPHNYJ | Initial Entry |

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:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261599**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-07-2020 17:28:00 (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-07-2020 17:28:00 (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-07-2020 17:28:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-07-2020 17:28:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-07-2020 17:28:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/7/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Sep-07-2020 17:28:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPTJVB | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Sep-07-2020 17:28:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPTJVB | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-07-2020 15:50:45 (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-07-2020 15:50:45 (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-07-2020 15:50:45 (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-07-2020 15:50:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/7/2020 13:18 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-07-2020 15:50:45 (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-07-2020 15:50:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-07-2020 15:50:45 (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-07-2020 15:50:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-07-2020 15:50:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 06-Jul-2020 21:53
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-07-2020 15:50:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT | Initial Entry |

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---|
| Oct-07-2020 06:36:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Closed per SITE response, added to PD tracker |
| Oct-06-2020 09:31:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Confirm date as correct |
| Oct-06-2020 09:06:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | PDQ: DOV at this visit is out of window (2 day) from DOV (07/Sep /2020) at VID1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate. |
| Oct-03-2020 09:38:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/2/2020 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-03-2020 09:38:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/2/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-03-2020 09:38:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: C Temperature Location:: FOREHEAD | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-03-2020 09:38:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Oct-03-2020 09:38:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.5 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-03-2020 09:38:29 (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 |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-03-2020 09:38:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/2/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined I 113 dentifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done:: | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-03-2020 09:38:48 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-03-2020 12:01:57 (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-03-2020 12:01:57 (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-03-2020 12:02:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-03-2020 12:01:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-03-2020 12:01:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/2/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-03-2020 12:02:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPVYTX | Initial Entry |

5.a Sample ID

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-03-2020 09:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-03-2020 09:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-03-2020 09:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Oct/2/2020 13:50 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-03-2020 09:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Oct-03-2020 09:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> LEFT | Initial Entry |

7. Route:

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-03-2020 09:39:49 (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 |
|--|-----------------|-------------------------|---|---------------|
| Oct-03-2020 09:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------------------|---------------------------|---------------|
| Oct-03-2020 09:39:49 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: YES | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Nov-03-2020 16:09:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/3/2020 | 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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-03-2020 18:00:27 (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-03-2020 18:00:27 (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-03-2020 18:00:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-03-2020 18:00:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-03-2020 18:00:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Nov/3/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-03-2020 18:00:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR78CT | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-03-2020 18:00:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR78CT | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-03-2020 18:00:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BS2VC9 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-03-2020 18:00:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BS2VC9 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-03-2020 18:00:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BS2VCB | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-03-2020 18:00:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BS2VCB | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|--|
| Nov-07-2020 12:55:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Nov-07-2020 12:51:38 (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. |
| Nov-07-2020 12:51:38 (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. |
| Nov-07-2020 12:51:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/7/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Nov-07-2020 12:51:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1226**Subject No:** 12261599**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Assessment:**

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/7/2020 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/6/2020 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|-----------------|
| Dec-15-2020 17:38:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: Nov/13/2020 | New Information |
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: NO | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-07-2020 12:53:16 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

4.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre sent: YES | Initial Entry |

4.b Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:16 (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 |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED SH : ORTNESS OF BREATH Symptom Present: NO | Initial Entry |

4.c Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SHORTNESS O F BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1226**Subject No:** 12261599**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54**4.d**

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: NO | Initial Entry |

4.d Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-07-2020 12:53:16 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO | Initial Entry |

4.e Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.f

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--|-----------------|
| Nov-11-2020 15:57:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: YES | New Information |
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO | Initial Entry |

4.f Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|-----------------|
| Nov-11-2020 15:57:56 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | New Information |
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

4.g Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARRHEA Symptom Present: NO | Initial Entry |

4.h Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-07-2020 12:53:16 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMITING Symptom Present: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

4.i Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-07-2020 12:53:16 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - Other: Coryza | Initial Entry |

5.a Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-07-2020 12:53:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Coryza | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020
Form: MICROBIOLOGY SPECIMEN - Audit Trail
Form Version: 06-Jul-2020 21:54
Form Status:
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-11-2020 16:00:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-11-2020 16:01:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/7/2020 | Initial Entry |
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-11-2020 16:00:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWABBED MATERIAL | Initial Entry |
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-11-2020 16:00:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NASOPHARYNX | Initial Entry |
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Nov-11-2020 16:01:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SEVERE ACUTE RESP SYNDROME C ORONAVIRUS 2 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Nov-11-2020 16:01:25 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-11-2020 16:00:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> OTHER | Initial Entry |
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

7. Test Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-11-2020 16:00:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> POSITIVE | Initial Entry |
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

8. Comments/Findings/Details:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-11-2020 16:00:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NALT Unknown | Initial Entry |
| Nov-11-2020 15:59:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Nov-07-2020 12:53:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12261599**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-07-2020 12:55:32 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-07-2020 12:55:32 (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 |
|--|-----------------|---------------------------|---|--|
| Nov-11-2020 16:18:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-11-2020 16:16:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-11-2020 16:16:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Nov/11/2020 | New Information |
| Nov-07-2020 12:55:32 (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 |
|--|-----------------|---------------------|--|-----------------|
| Nov-11-2020 16:16:32 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Nov-07-2020 12:55:32 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: The nasal swab was performed on site and the information is on "SWAB PFE" item | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-11-2020 16:18:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: RW91559 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Nov-11-2020 16:18:45 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RW91559 | Initial Entry |

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12261599**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-07-2020 12:55:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-07-2020 12:55:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|--|
| Nov-07-2020 12:55:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-07-2020 12:55:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-07-2020 12:55:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Nov/7/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:55:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR6946 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-07-2020 12:55:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR6946 | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO | Initial Entry |

I.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

I.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO | Initial Entry |

I.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROOM | Initial Entry |

I.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

I.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO | Initial Entry |

I.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

I.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | Initial Entry |

I.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

I.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.e

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261599**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO | Initial Entry |

1.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:53:57 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO | Initial Entry |

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-07-2020 12:53:57 (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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:57 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:53:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
|---|-----------------|---------------------|--------------------------|---------------|

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. What is the treatment Identifier?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Concomitant Non-drug Treatment Pre-specified:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6. Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020
Form: ILLNESS DETAILS - eCRF Audit Trail History
Form Version: 06-Jul-2020 21:52
Form Status: Data Complete, Frozen, Verified
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Nov-07-2020 12:54:29 (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 |
|--|-----------------|---------------------------|---|--|
| Nov-16-2020 08:44:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Rupal N Shah (b) (4) | Query 2: Closed | Response satisfies query |
| Nov-16-2020 08:43:43 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Rupal N Shah (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-16-2020 08:00:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |
| Nov-16-2020 08:00:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-16-2020 08:00:34 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Respiratory Illness Diagnosis</i> COVID-19 Date of Diagnosis: Nov/7/2020 | Transcription Error |
| Nov-16-2020 07:29:08 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Rupal N Shah (b) (4) | Query 2: Opened | CLIQUEY: Please confirm the date of the diagnosis as the date of local COVID-19 test collection is 07Nov2020 |
| Nov-16-2020 07:24:51 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Rupal N Shah (b) (4) | Query 1: Opened | CLIQUEY: Please update the diagnosis as diagnosis (ie. COVID-19), should not be test result. |
| Nov-13-2020 15:32:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Respiratory Illness Diagnosis</i> | New Information |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--|-----------------|
| | | | COVID-19 RT-PCR TEST POSITIVE Date of Diagnosis: Nov/13/2020 | |
| Nov-13-2020 15:30:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Respiratory Illness Diagnosis</i> COVID-19 RT-PCR TEST POSITIVE Date of Diagnosis: Nov/7/2020 | New Information |
| Nov-11-2020 15:59:33 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Respiratory Illness Diagnosis</i> COVID-19 Date of Diagnosis: Nov/7/2020 | New Information |
| Nov-07-2020 12:54:29 (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 |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-07-2020 12:54:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Subcategory of Clinical Event:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Was a diagnosis obtained?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1226**Subject No:** 12261599**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Lab Panel:**

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

5.a Sponsor ID:

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
|--|-----------------|---------------------|--------------------------------------|---------------|

5.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Lab Normal Range: | Not Applicable |
|--|--|--|--------------------------|----------------|

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|--------------------------|--------------------|
| | | | Not Done:: | Not Applicab le |
| | | | Lab Normal Range: | Not Applicab le |

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicab le Test:: Not Applicab le | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Result: | Not Applicable |
| | | | Not Done: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|---|--|
| | | | Test:: Not Applicab le Result:: Not Applicab le Not Done:: Not Applicab le Lab Normal Range: Not Applicab le | |
|--|--|--|---|--|

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Nov-07-2020 12:54:54 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:49

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|----------------------------------|------------------|------------------------------------|----------------|
| (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Sponsor-Defined Identifier: | Not Applicable |
| | | Test:: | Not Applicable |
| | | Result:: | Not Applicable |
| | | Not Done:: | Not Applicable |
| | | Lab Normal Range: | Not Applicable |

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:54:54 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020
Form Version: 21-Aug-2020 02:51
Site No: 1226
Subject No: 12261599
Generated By: (b) (4)
Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

5.a Sponsor ID:

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
|--|-----------------|---------------------|--------------------------------------|---------------|

5.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form Version:** 21-Aug-2020 02:51**Site No:** 1226**Subject No:** 12261599**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54**5.b Sponsor ID:**

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Lab Normal Range: | Not Applicable |
|--|--|--|--------------------------|----------------|

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|--------------------------|--------------------|
| | | | Not Done:: | Not Applicab le |
| | | | Lab Normal Range: | Not Applicab le |

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicab le Test:: Not Applicab le | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|-------------------|----------------|
| | | | Result: | Not Applicable |
| | | | Not Done: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|--|--|--|---|
| | | | Test:: Not Applicab le Result:: Not Applicab le Not Done:: Not Applicab le Lab Normal Range: Not Applicab le |
|--|--|--|---|

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Nov-07-2020 12:55:16 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | |
|----------------------------------|------------------|------------------------------------|----------------|
| (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Sponsor-Defined Identifier: | Not Applicable |
| | | Test:: | Not Applicable |
| | | Result:: | Not Applicable |
| | | Not Done:: | Not Applicable |
| | | Lab Normal Range: | Not Applicable |

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Lab Normal Range: | Not Applicable |
|--|--|--|--------------------------|----------------|

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-07-2020 12:55:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020
Form: VITAL SIGNS - COVID - Audit Trail
Form Version: 21-Aug-2020 02:50
Form Status:
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/7/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Systolic:: 13 3 Diastolic:: 92 Respiratory Rate in respirations/m inute: 16 Heart Rate in beats/minute: 89 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 133 | Initial Entry |

2.a Diastolic:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------|---|
| Nov-09-2020 19:12:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-09-2020 15:34:58 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | The SI evaluated as not clinically significant. |
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Diastolic BP 92 is outside of Normal Range 60 - 90. |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 92 | Initial Entry |
|--|-----------------|---------------------|--------------------------|---------------|

2.a Respiratory Rate in respirations/minute:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 16 | Initial Entry |

2.a Heart Rate in beats/minute:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-07-2020 12:55:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 89 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020
Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Form Version: 21-Aug-2020 02:51
Form Status:
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-07-2020 12:57:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-07-2020 12:57:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/7/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 12:57:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Oxygen Saturation: 93.0 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-07-2020 12:57:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-07-2020 12:57:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 93.0 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date Time of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Arterial Blood Gases PaO2 (mmHg):

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. FiO2 (Fraction of Inhaled Oxygen):

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

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).

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6. Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/07/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Type of Imaging Exam:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-07-2020 12:58:55 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|-----------------------------|---|
| Mar-25-2021 03:18:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Query to be raised post BLA. PD tracker will be updated accordingly. |
| Mar-16-2021 03:57:23 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued:Candidate | PDQ RQ1: As per Query response, CONVA visit will be checked after 30Mar21. |
| Mar-15-2021 10:01:00 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | The CONVA is scheduled to 30MAR2021 |
| Mar-15-2021 07:30:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | PDQ: Convalescent visit is missing and 35+ days (37) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify. |
| Feb-08-2021 12:15:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Feb-08-2021 08:24:07 (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. |
| Feb-08-2021 08:24:07 (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. |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|------------------|----------------------------------|---------------|
| Feb-08-2021 08:24:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/6/2021 | Initial Entry |
|--|-----------------|------------------|----------------------------------|---------------|

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Feb-08-2021 08:24:07 (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 Feb/06/2021

Form Version: 14-Jan-2021 02:23

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1. Date of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/6/2021 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/4/2021 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: NO | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------|---------------|
| Feb-08-2021 08:25:19 (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 |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.b

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form Version: 14-Jan-2021 02:23

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre sent: YES | Initial Entry |
|--|-----------------|------------------|---|---------------|

4.b Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:25:19 (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 |
|--|-----------------|------------------|---------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms NEW OR INCREASED SH : ORTNESS OF BREATH Symptom Present: NO | Initial Entry |

4.c Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form Version: 14-Jan-2021 02:23

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|-------|--|--|---------------------|--|
| Aires | | | Symptom Present: NO | |
|-------|--|--|---------------------|--|

4.d Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Feb-08-2021 08:25:19 (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 |
|---|-----------------|------------------|-----------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: YES | Initial Entry |

4.e Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form Version: 14-Jan-2021 02:23

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

4.f Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES | Initial Entry |

4.g Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARRHEA Symptom Present: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1226**Subject No:** 12261599**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54**4.h Symptoms:**

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Feb-08-2021 08:25:19 (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 |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMITING Symptom Present: NO | Initial Entry |

4.i Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Feb-08-2021 08:25:19 (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 |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:25:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:25:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - Other: Runny nose | Initial Entry |

5.a Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Feb-08-2021 08:25:31 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Runny nose | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

7. Test Result:

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
|--|-----------------|------------------|--------------------------------------|---------------|

8. Comments/Findings/Details:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:25:41 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-08-2021 08:26:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Feb-08-2021 08:26:07 (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 |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:07 (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 |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:26:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Collected on site, recorded at SWAB PFE | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12261599**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-08-2021 12:15:59 (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-08-2021 12:15:59 (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-08-2021 12:16:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-08-2021 12:15:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-08-2021 12:15:59 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/6/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 12:16:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRH04K | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Feb-08-2021 12:16:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRH04K | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO | Initial Entry |

I.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

I.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO | Initial Entry |

I.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROOM | Initial Entry |

I.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

I.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO | Initial Entry |

I.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

I.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | Initial Entry |

I.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

I.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.e

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261599**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO | Initial Entry |

1.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:26:18 (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 |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.f

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO | Initial Entry |

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------|---------------|
| Feb-08-2021 08:26:18 (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 |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:18 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
|--|-----------------|------------------|--------------------------|---------------|

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-08-2021 08:26:27 (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 |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:27 (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 |
|--|-----------------|------------------|-------------------------|---------------|
| Feb-08-2021 08:26:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021
Form: VITAL SIGNS - COVID - Audit Trail
Form Version: 21-Aug-2020 02:50
Form Status:
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

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| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------|--------|
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/6/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Systolic:: 13 9 Diastolic:: 93 Respiratory Rate in respirations/m inute: 16 Heart Rate in beats/minute: 78 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|---------------|
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 139 | Initial Entry |

2.a Diastolic:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|-------------------|---|
| Feb-08-2021 15:21:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-08-2021 08:27:18 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | oot clinically significat |
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Diastolic BP 93 is outside of Normal Range 60 - 90. |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 93 | Initial Entry |
|--|-----------------|------------------|--------------------------|---------------|

2.a Respiratory Rate in respirations/minute:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 16 | Initial Entry |

2.a Heart Rate in beats/minute:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-08-2021 08:26:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 78 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021
Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Form Version: 21-Aug-2020 02:51
Form Status:
Site No: 1226
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:54

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| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------|--------|
| Feb-08-2021 08:27:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/06/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

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

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-08-2021 08:27:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Oxygen Saturation: 99.0 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Feb-08-2021 08:27:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------|---------------|
| Feb-08-2021 08:27:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 99.0 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History
Dec/15/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-15-2020 16:46:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/15/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-15-2020 16:46:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_A1 | Initial Entry |

Header Text: C4591001
Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/15/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261599 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-15-2020 17:16:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Dec-15-2020 17:16:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|--|
| Dec-15-2020 17:17:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-15-2020 17:16:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Dec-15-2020 17:16:53 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Dec/15/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Dec-15-2020 17:17:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGTHM | Initial Entry |

5.a Sample ID

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

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/15/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-15-2020 17:17:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BSF217 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Dec-15-2020 17:17:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BSF217 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Dec-15-2020 17:17:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BSF21D | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------|---------------|
| Dec-15-2020 17:17:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BSF21D | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/08/2020 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Sep-08-2020 15:11:07 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/8/2020 | Initial Entry |

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/08/2020 **Form:** UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I. Assessments

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|--|
| Sep-08-2020 15:13:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-08-2020 15:11:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate. |
| Sep-08-2020 15:11:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CONTACT OUTCOME | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/08/2020 **Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Contact Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-08-2020 15:13:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Sep-08-2020 15:13:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Sep/8/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION | Initial Entry |

3. Comments:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Sep-08-2020 15:13:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Contact made due to covid-19 symptom alert. Patient refers muscle pain on 07Sep2020 (grade1), related to vaccine reactogenicity. | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Nov-03-2020 16:10:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/3/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-03-2020 16:10:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------------|---------------|
| Nov-03-2020 16:10:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Feb-09-2021 17:33:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/5/2021 | Initial Entry |

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261599

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Feb-09-2021 17:33:27 (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 and NOT confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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| Date | Location | User | Value | Reason |
|--|-----------------|---|--------------|--------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Form Created | |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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| Date | Location | User | Value | Reason |
|--|-----------------|---|--------------|--------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Form Created | |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: myalgia | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/7/2020 20:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Sep/10/2020 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
|--|-----------------|---------------------|--------------------------|---------------|

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:42:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 2 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> fatigue | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sep/7/2020 20:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO End Date Time: Sep/10/2020 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 1 | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

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

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
|--|-----------------|---------------------|--------------------------|---------------|

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:43:38 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: corneal ulcer right eye | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/20/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------------|
| Oct-08-2020 08:03:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Sep/27/2020 UNK:UNK | Transcription Error |
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

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

090177e196ae405d\Final\On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| | | | | |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |
|--|-----------------|---------------------|-------------------------|---------------|

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify prolonged use of contact lens | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|--|
| Oct-08-2020 08:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Oct-08-2020 08:27:40 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | New Information |
| Oct-08-2020 08:03:39 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE corneal ulcer right eye: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present. |
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERING/RESOLVING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-03-2020 09:47:52 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae405d\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Feb-09-2021 17:33:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/5/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-09-2021 17:33:11 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Nov-03-2020 16:10:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-07-2020 15:50:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Sep-07-2020 15:43:29 (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 |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-03-2020 16:10:06 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Nov/3/2020 | Initial Entry |
| Sep-07-2020 15:50:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/7/2020 | Initial Entry |
| Sep-07-2020 15:43:29 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/7/2020 | Initial Entry |

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Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261599

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Nov-06-2020 14:58:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |

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