

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1226

Subject No: 12262272

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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 Oct/17/2020
----	--------------	--

Header Text: C4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY
Form Version: 15-Sep-2020 21:54 **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: 12262272 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12262272]
2.	Birth Date:	(b) (6)/1998
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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/17/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1226

Subject No: 12262272

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 15-Sep-2020 21:52
Site No: 1226
Subject No: 12262272
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	Oct/17/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001	Form: HIV STATUS
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 15-Sep-2020 21:57	Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Site No: 1226	Subject Initials: ---
Subject No: 12262272	Generated Time (GMT): 29-Mar-2021 13:54
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1226

Subject No: 12262272

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:	Oct/17/2020
2.	Weight:	[62.5]
3.	Unit:	kg
4.	Height:	[170.0]
5.	Unit:	cm
6.	Body Mass Index:	[21.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12262272
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 :	Oct/17/2020
2.	Randomization Number:	[109494]
3.	Randomization Group:	[]

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12262272
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: Oct/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRT5MX]
5.b	Sample ID	[BRT5MW]
5.c	Sample ID	[BR6NJ3]

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12262272
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/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR77YH]
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:04
Site No: 1226
Subject No: 12262272
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:	Oct/17/2020 10:24
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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Site No: 1226	Subject Initials: ---
Subject No: 12262272	Generated Time (GMT): 29-Mar-2021 13:54
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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	Nov/7/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1226

Subject No: 12262272

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:	Nov/7/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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: 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	[BR6940]
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

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:	Nov/7/2020 10:35
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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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	Dec/23/2020
2.	Erroneous Visit	

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001
Visit: V3_MONTH1_POSTVAX2_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12262272
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: Dec/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP990W]
5.b	Sample ID	[BSF281]
5.c	Sample ID	[BSF282]

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

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: 12262272

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
----	-------------------------	---------

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

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

Site No: 1226

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

Subject No: 12262272

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:	Oct/27/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/29/2020

Symptoms

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

Symptoms - Other

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

5.	Symptoms - Other Text:	[]
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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 Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Nov/07/2020

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: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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

Microbiology Specimen

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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[The sponsor gave the instruction to create the COVID ILLNESS FORM due to the symptom, but the subject did not come specifically to the visit; also nasal swab were not collected]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unsheduled 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: 12262272

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[The sponsor gave the instruction to create the COVID ILLNESS FORM due to the symptom, but the subject did not came specifically to the visit; also nasal swab were not collected]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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

Site No: 1226

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

Subject No: 12262272

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
----	--	----

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

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: Not Started

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Respiratory Treatment

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020 **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: 12262272

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?	NO
3.	Toxicity Grade:	1

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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 1 - Unscheduled Visit on Nov/07/2020 **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: 12262272

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 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1226

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

Subject No: 12262272

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

Header Text: C4591001

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

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1226

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

Subject No: 12262272

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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1226

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

Subject No: 12262272

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	Test:	Result:	Repeating Pages

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Not Started

Site No: 1226

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

Subject No: 12262272

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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Nov/07/2020

Form Version: 10-Oct-2020 15:59

Form Status: Not Started

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Not Started

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1226

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

Subject No: 12262272

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.				Repeating Pages

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: Not Started

Site No: 1226

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

Subject No: 12262272

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):	[]

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

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: 12262272

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

Header Text: C4591001

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

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-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: 12262272

Subject Initials: ---

Generated By: (b) (4)

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?	

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Nov/07/2020

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: 12262272

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 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Feb/20/2021

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: 12262272

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/20/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Feb/20/2021

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: 12262272

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: Feb/20/2021
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	[BRK719]
5.b	Sample ID	[BSCWW8]
5.c	Sample ID	[BSCWW7]

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

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: 12262272

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: 12262272

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 - New Unscheduled Visit

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: 12262272

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 - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1226

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

Subject No: 12262272

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 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: 12262272 **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:	

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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?	

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1226

Subject No: 12262272

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:	[]

Header Text: C4591001
Visit: Unplanned Vaccination - Unscheduled **Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01 **Form Status:** Not Started
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12262272 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12262272

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 :	Dec/23/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

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	Jan/21/2021
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, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

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

Disposition - Follow-Up

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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	Jan/23/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER 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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/23/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER 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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER 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](#)

Disposition - Screening for Further Vaccination

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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: Jan/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR67XB]
5.b	Sample ID	[BSF1KC]
5.c	Sample ID	[BSF1KD]

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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: Jan/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR67WS]
-----	-----------	----------

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12262272

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/23/2021 14:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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	Feb/20/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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: Feb/20/2021
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	[BRK70W]
-----	-----------	----------

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12262272

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/20/2021 12:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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	Mar/22/2021
2.	Erroneous Visit	

Header Text: C4591001
Visit: V103_MONTH1
Form Version: 22-Apr-2020 21:04
Site No: 1226
Subject No: 12262272
Generated By: (b) (4)

Form: CONTACT OUTCOME
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](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/22/2021
3.	Comments:	[]

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: CONTACT OUTCOME

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: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: CONTACT OUTCOME

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: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

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: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Mar/22/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 12262272

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. DELETED	ADVERSE EVENT	1	Myalgia	Oct/27/2020 UNK:UNK	NO End Date Time: Oct/29/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	myalgia	Jan/24/2021 UNK:UNK	NO End Date Time: Jan/27/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	left axillary lymph node enlargement	Jan/24/2021 UNK:UNK	NO End Date Time: Jan/27/2021 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	fatigue	Feb/21/2021 UNK:UNK	NO End Date Time: Feb/21/2021 UNK:UNK	Repeating Pages

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

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

Subject Initials: ---

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

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Myalgia]
4.	Start Date Time:	Oct/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/29/2020 UNK:UNK
6.	Toxicity Grade:	4
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: [unknown etiology]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

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

Subject Initials: ---

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

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

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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)	[myalgia]
4.	Start Date Time:	Jan/24/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/27/2021 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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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	[]

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12262272**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)	[left axillary lymph node enlargement]
4.	Start Date Time:	Jan/24/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/27/2021 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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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	[]

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12262272**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, 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:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fatigue]
4.	Start Date Time:	Feb/21/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/21/2021 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

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1226
Subject No: 12262272
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, 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	[]

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: 12262272

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1226

Subject No: 12262272

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	[]

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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:	//

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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?	

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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?	

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: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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:	//

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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 :	Jan/21/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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:	//
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Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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	Dec/23/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

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
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Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

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	Mar-23-2021 15:00:55 (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: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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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Item	Date	User	Comment
Form	Oct-17-2020 13:04:53 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

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](#)

Item	Date	User	Comment
Form	Oct-17-2020 13:05:14 (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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

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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Item	Date	User	Comment
Form	Jan-23-2021 15:04:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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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	Mar-23-2021 15:00:55 (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	Mar-22-2021 16:22:57 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Mar-04-2021 12:29:45 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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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-22-2021 09:32:22 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Feb-12-2021 16:50:18 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

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

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.

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1226

Subject No: 12262272

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
Oct-17-2020 13:03:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-17-2020 13:03:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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
Oct-17-2020 13:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/17/2020	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12262272

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
Oct-17-2020 13:03:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12262272	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-17-2020 13:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1998	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-17-2020 13:04:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-17-2020 13:04:25 (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
Oct-17-2020 13:04:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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-17-2020 13:04:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12262272

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: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-17-2020 13:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 15-Sep-2020 21:57
Site No: 1226
Subject No: 12262272
Generated By: (b) (4)
Form: HIV STATUS - 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 - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-17-2020 13:05:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1226

Subject No: 12262272

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

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1. Date:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 62.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 170.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.6	Initial Entry

7.a

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1226

Subject No: 12262272

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

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (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: FOREHEA : D	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (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
Oct-17-2020 13:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-17-2020 13:05:42 (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
Oct-17-2020 13:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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
Oct-17-2020 13:06:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-17-2020 13:06:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 109494	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: 12262272

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-17-2020 16:56:36 (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-17-2020 16:56:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-17-2020 16:56:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-17-2020 16:56:36 (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-17-2020 16:56:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-17-2020 16:56:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRT5MX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

Oct-17-2020 16:56:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRT5MX	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-17-2020 16:56:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRT5MW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-17-2020 16:56:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRT5MW	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-17-2020 16:56:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6NJ3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-17-2020 16:56:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6NJ3	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

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-17-2020 16:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-17-2020 16:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-17-2020 16:33:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-17-2020 16:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-17-2020 16:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-17-2020 16:33:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR77YH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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-17-2020 16:33:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR77YH	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

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-17-2020 13:06:40 (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
Oct-17-2020 13:06:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-17-2020 13:06:40 (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
Oct-17-2020 13:06:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020 10:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-17-2020 13:06:40 (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
Oct-17-2020 13:06:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

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

Date	Location	User	Value	Reason
Oct-17-2020 13:06:40 (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-17-2020 13:06:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION 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-17-2020 13:06:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12262272

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
Oct-17-2020 13:06:46 (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: 12262272

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
Nov-07-2020 12:14:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1226

Subject No: 12262272

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
Nov-07-2020 12:14:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/7/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-07-2020 12:14:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 36.4 Temperature Unit: C Temperature Location FOREHEA :: D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-07-2020 12:14:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-07-2020 12:14:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-07-2020 12:14:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-07-2020 12:14:48	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1226

Subject No: 12262272

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

(UTC-03:00) City of
Buenos Aires

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

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: 12262272

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-07-2020 12:38:13 (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 12:38:13 (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 12:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-07-2020 12:38:13 (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 12:38:13 (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 12:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR6940	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

Nov-07-2020 12:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6940	Initial Entry
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

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
Nov-07-2020 12:15:21 (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
Nov-07-2020 12:15:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-07-2020 12:15:21 (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
Nov-07-2020 12:15:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020 10:35	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-07-2020 12:15:21 (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
Nov-07-2020 12:15:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

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

Date	Location	User	Value	Reason
Nov-07-2020 12:15:21 (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
Nov-07-2020 12:15:21 (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
Nov-07-2020 12:15:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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
Dec-29-2020 04:20:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical Review
Dec-28-2020 10:20:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Date is correct. Subject came out of the window due unavailability.
Dec-24-2020 02:35:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 11 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Dec-23-2020 14:52:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Dec/23/2020	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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:** 12262272**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
Dec-23-2020 17:49:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-23-2020 17:49:51 (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-23-2020 17:50:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-23-2020 17:49:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-23-2020 17:49:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-23-2020 17:50:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP990W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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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: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

Dec-23-2020 17:50:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP990W	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-23-2020 17:50:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSF281	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-23-2020 17:50:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSF281	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-23-2020 17:50:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSF282	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-23-2020 17:50:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSF282	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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
Feb-23-2021 04:52:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	CONVA received hence closed
Feb-16-2021 04:40:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Candidate	PDQ RQ2: Thank you for the response, Please respond to query once contact made and please update the details once available. Else clarify.
Feb-15-2021 16:18:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Site is in contact with CRA to clarify this question about the late convalescent visits. Once we had a return, it is going to be updated.
Feb-08-2021 08:17:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	PDQ RQ1: Thank you for the response, Please respond to query once contact made and please update the details once available. Else clarify.
Feb-05-2021 12:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	The visit will be scheduled as soon as possible.
Feb-04-2021 07:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	PDQ: Convalescent visit is missing and 35+ days (89) have passed since COVID Illness Visit. If visit occurred record the data as a matching CONVA visit; if the visit did not occur attempt to schedule

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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:** 12262272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54

				the visit and obtain the CONVA sample else clarify.
Nov-11-2020 05:22:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	As per the response in #4 in Swab form
Nov-10-2020 16:23:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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-10-2020 16:23:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020	data entry correction
Nov-10-2020 06:12:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Deleted as per comment on SWAB, updated PD tracker
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-09-2020 15:41:15 (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-09-2020 15:41:15 (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-09-2020 15:41:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020	Initial Entry

3. COVID-19 Illness Visit:

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: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-09-2020 15:41:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1226**Subject No:** 12262272**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
Nov-12-2020 05:13:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Nov-11-2020 17:18:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirm date as correct both 07Nov2020 as reported
Nov-11-2020 08:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: Please provide the reason why Date of assessment (7/Nov /2020) is not same as Date of Visit (27/Oct /2020) in query response. Update if required. Else clarify.
Nov-10-2020 16:23:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Nov-10-2020 09:40:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Date of assessment (7/Nov /2020) is not same as Date of Visit (27/Oct /2020). Please check and correct.
Nov-09-2020 15:42:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Nov-09-2020 15:42:24 (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
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Header Text: C4591001

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

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020	Initial Entry
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3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Oct/29/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (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-09-2020 15:42:24 (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-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Present: NO	Initial Entry

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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/07/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12262272**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (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-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED s: SHORTNESS OF BREA TH Symptom NO Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: 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:** 12262272**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.d Symptoms:**

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (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-09-2020 15:42:24 (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-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom YES Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE P AIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL	Initial Entry

Header Text: C4591001

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

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

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Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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			Symptom Present:	
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4.f Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (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-09-2020 15:42:24 (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-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (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-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: C4591001

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

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

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Generated By: (b) (4)

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(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Symptoms: DIARRHEA Symptom Present: NO	
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4.h Symptoms:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:24 (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-09-2020 15:42:24 (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-09-2020 15:42:24 (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
Nov-09-2020 15:42:24 (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-09-2020 15:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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

Site No: 1226

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

Subject No: 12262272

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-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

7. Test Result:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-09-2020 15:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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: 12262272

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
Nov-09-2020 15:43:06 (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-09-2020 15:43:06 (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-09-2020 15:43:06 (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-09-2020 15:43:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The sponsor gave the instruction to create the COVID ILLNESS FORM due to the symptom, but the subject did not come specifically to the visit; also nasal swab were not collected	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

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-09-2020 15:43:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-09-2020 15:43:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-09-2020 15:43:20 (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-09-2020 15:43:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The sponsor gave the instruction to create the COVID ILLNESS FORM due to the symptom, but the subject did not come specifically to the visit; also nasal swab were not collected	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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I.a

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30 (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-09-2020 15:43:30 (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-09-2020 15:43:30 (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-09-2020 15:43:30 (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

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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

Site No: 1226

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

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Subject Initials: ---

Generated By: (b) (4)

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I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30 (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-09-2020 15:43:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30 (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-09-2020 15:43:30 (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-09-2020 15:43:30 (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-09-2020 15:43:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence of Visits or Contacts:	
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I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30 (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-09-2020 15:43:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30 (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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Type of Practitioner: OTH R	
			Occurrence of Visits or Contacts: NO	

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-09-2020 15:43:30 (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-09-2020 15:43:30 (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
Nov-09-2020 15:43:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (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

Site No: 1226

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

Subject No: 12262272

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-09-2020 15:43:39 (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-09-2020 15:43:39 (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-09-2020 15:43:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History on Feb/20/2021

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: 12262272

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-22-2021 09:32:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/20/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-22-2021 09:32:22 (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 Feb/20/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos
Medicos Ltda**Subject No:** 12262272**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
Feb-22-2021 10:34:36 (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-22-2021 10:34:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 10:34:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 10:34:36 (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-22-2021 10:34:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 10:34:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRK719	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Feb/20/2021 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: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 10:34:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRK719	Initial Entry
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5.b

Date	Location	User	Value	Reason
Feb-22-2021 10:35:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSCWW8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 10:35:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSCWW8	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 10:35:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSCWW7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 10:35:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSCWW7	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12262272

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
Dec-23-2020 14:52:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-23-2020 14:52:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-23-2020 14:52:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

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
Jan-23-2021 15:03:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

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: 12262272

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
Jan-23-2021 15:03:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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
Jan-23-2021 15:03:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/23/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER 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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I. Consent Was:

Date	Location	User	Value	Reason
Jan-23-2021 15:04:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/23/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-23-2021 15:04:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/23/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-23-2021 15:04:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-23-2021 15:04:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

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
Jan-23-2021 15:11:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-23-2021 15:11:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-23-2021 15:11:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-23-2021 15:11:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-23-2021 15:11:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-23-2021 15:11:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR67XB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

Jan-23-2021 15:11:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR67XB	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jan-23-2021 15:12:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSF1KC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-23-2021 15:12:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSF1KC	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-23-2021 15:12:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSF1KD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-23-2021 15:12:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSF1KD	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

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
Jan-23-2021 15:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-23-2021 15:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-23-2021 15:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-23-2021 15:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-23-2021 15:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-23-2021 15:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR67WS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

Jan-23-2021 15:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR67WS	Initial Entry
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12262272

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
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/23/2021 14:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12262272

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

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-23-2021 15:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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
Feb-23-2021 12:39:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 07:23:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-23-2021 06:03:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit V102_VAX4 is out of window for 5 days from V101_VAX3 Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Feb-22-2021 09:33:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/20/2021	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

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
Feb-22-2021 11:03:08 (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-22-2021 11:03:08 (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-22-2021 11:03:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 11:03:08 (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-22-2021 11:03:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 11:03:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRK70W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 11:03:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRK70W	Initial Entry
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090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12262272

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
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/20/2021 12:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12262272

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

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 09:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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
Mar-22-2021 16:22:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/22/2021	Initial Entry

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: CONTACT OUTCOME - 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. Contact Type:

Date	Location	User	Value	Reason
Mar-22-2021 16:23:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-22-2021 16:23:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/22/2021	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262272

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-22-2021 16:23:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/22/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-22-2021 16:23:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-22-2021 16:23:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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

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

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Date	Location	User	Value	Reason
Nov-09-2020 15:44:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Entred on covid illness form
Nov-07-2020 12:19:25 (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: 12262272

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
Feb-22-2021 09:35:01 (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: 12262272

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
Feb-22-2021 09:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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
Mar-22-2021 16:24:14 (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: 12262272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

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

Subject Initials: ---

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

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

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I. Category:

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (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
Nov-07-2020 12:19:25 (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
Nov-10-2020 06:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 15:44:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Entred on covid illness form
Nov-09-2020 09:53:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clinical: please consider if this could have been a COVID related symptom and whether a Potential COVID illness Visit should be completed, thank you.
Nov-07-2020 12:19:25 (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
Nov-07-2020 12:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020 UNK:UNK	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

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

Subject Initials: ---

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

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

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/29/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (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
Nov-07-2020 12:19:25 (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
Nov-07-2020 12:19:25 (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:	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

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

Subject Initials: ---

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

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

			OTHER	
			<i>If Other, specify:</i>	
			unknown etiology	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-07-2020 12:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12262272**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[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-22-2021 09:35:01 (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
Feb-22-2021 09:35:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-22-2021 09:35:01 (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
Feb-22-2021 09:35:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/24/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 09:35:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/27/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-22-2021 09:35:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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
Feb-22-2021 09:35:01 (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
Feb-22-2021 09:35:01 (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
Feb-22-2021 09:35:01 (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
Feb-22-2021 09:35:01 (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
Feb-22-2021 09:35:01 (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
Feb-22-2021 09:35:01	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	NO	
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-22-2021 09:35:01 (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
Feb-22-2021 09:35:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

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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
Feb-22-2021 09:37:19 (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
Feb-22-2021 09:37:19 (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
Feb-22-2021 09:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: left axillary lymph node enlargement	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-22-2021 09:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/24/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 09:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/27/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-22-2021 09:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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
Feb-22-2021 09:37:19 (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
Feb-22-2021 09:37:19 (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
Feb-22-2021 09:37:19 (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
Feb-22-2021 09:37:19 (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
Feb-22-2021 09:37:19 (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
Feb-22-2021 09:37:19	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

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

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	NO	
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-22-2021 09:37:19 (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
Feb-22-2021 09:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, 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
Mar-22-2021 16:24:14 (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
Mar-22-2021 16:24:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-22-2021 16:24:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-22-2021 16:24:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/21/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-22-2021 16:24:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/21/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-22-2021 16:24:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, 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
Mar-22-2021 16:24:14 (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
Mar-22-2021 16:24:14 (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
Mar-22-2021 16:24:14 (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
Mar-22-2021 16:24:14 (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
Mar-22-2021 16:24:14 (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
Mar-22-2021 16:24:14	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262272

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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)	NO	
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-22-2021 16:24:14 (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
Mar-22-2021 16:24:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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
Jan-23-2021 15:03:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-23-2021 15:03:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262272

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
Dec-23-2020 14:52:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-17-2020 13:06:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-17-2020 13:05:04 (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
Dec-23-2020 14:52:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/23/2020	Initial Entry
Oct-17-2020 13:06:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/17/2020	Initial Entry
Oct-17-2020 13:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/17/2020	Initial Entry

090177e196ae4058\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262272

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

Subject Initials: ---

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Dec-08-2020 15:22:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry