

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12262253

**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/16/2020
----	--------------	--

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** DEMOGRAPHY

**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](#)

**Demography**

1.	Subject ID	[12262253]
2.	Birth Date:	(b) (6)/1953
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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/16/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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 _____
----	--	-------------------------

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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/16/2020
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:** 12262253

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[systemic arterial hypertension]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[vasectomy]
	Start Date:	UNK/UNK/1985
	Ongoing:	NO End Date: UNK/UNK/1985
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[pre-diabetes mellitus]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[obesity]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES



**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** HIV STATUS

**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](#)

**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:** 12262253

**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/16/2020
2.	Weight:	[100.5]
3.	Unit:	kg
4.	Height:	[173.7]
5.	Unit:	cm
6.	Body Mass Index:	[33.3]

**Vital Signs Details**

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

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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/16/2020
2.	Randomization Number:	[270154]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
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	[BR77XW]
5.b	Sample ID	[BRT5LB]
5.c	Sample ID	[BRT5LC]

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12262253**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
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	[BR77XP]
-----	-----------	----------

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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/16/2020 13:51
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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262253

**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/4/2020
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/4/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.1]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12262253**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR78FS]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262253

**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/4/2020 12:10
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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

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

**Site No:** 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12262253 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site No:** 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12262253 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRGTBT]
5.b	Sample ID	[BSF1DB]
5.c	Sample ID	[BSF1DC]

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

**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](#)

**Date of Visit**

1.	Date of Visit	Dec/25/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

**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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Dec/25/2020
2.	Date of First Symptom Started:	Dec/24/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/10/2021

**Symptoms**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

4.f	Symptoms:	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
<b>Symptoms - Other</b>		
5.a	Symptoms - Other Text:	[increased body temperature (37.3C)]



**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

### Microbiology Specimen

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[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:	[Patient outside the country]

**Aliquot**

Please enter barcode for each aliquot.

5-a	Sample ID	[BP993J]
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262253**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**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](#)**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:	[Patient out of country]

**Aliquot**

Please enter barcode for each aliquot.

5-a	Sample ID	[BP993J]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION

**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

[eCRF Audit Trail History](#)

**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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
<b>Health Care Utilization Other</b>		
2.	Other Type of Practitioner Specify:	[ ]
<b>Health Care Utilization</b>		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

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**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatm ent	Treatm ent	Start D ate	Form Instanc e
1.						<a href="#">Repeating Pages</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** RESPIRATORY 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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**Respiratory Treatment**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS

**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

[eCRF Audit Trail History](#)

**Illness Details**

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

**Header Text:** C4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

**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:	

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**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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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

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**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

**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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** VITAL SIGNS - COVID

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

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**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Oxygenation Parameters**

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

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**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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

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**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Imaging**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

**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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**Date of Visit**

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

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
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	[BR686N]
5.b	Sample ID	[BSCW5F]
5.c	Sample ID	[BSCW5D]

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226 **Site Name:** (1226) CEPIC - Centro Paulista de  
Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12262253 **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:** 12262253**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

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**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:** 12262253      **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:** 12262253    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 13:54

**Unplanned Assessments**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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?	

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME - MONTH 6

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** C4591001

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

Unscheduled

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/23/2021
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[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
----	---	--

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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:** 12262253

**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/5/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/5/2021
----	--------------	---

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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 _____
----	--	-------------------------

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Feb/5/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[collection performed during the convalescence visit performed on the same day]

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**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:** 12262253**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
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	[BRH01K]
-----	-----------	----------

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**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/5/2021 12:50
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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12262253

**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/26/2021
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
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	[BR613N]
-----	-----------	----------

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12262253

**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/26/2021 10:45
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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1226

**Subject No:** 12262253

**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:** V103\_MONTH1

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

**Site No:** 1226

**Subject No:** 12262253

**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:** V104\_MONTH6

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

**Site No:** 1226

**Subject No:** 12262253

**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:** 12262253

**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:** 12262253

**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:** 12262253

**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:** Not Started

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Disposition - Treatment**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Nephrolithiasis	Jan/1/2021 UNK:UNK	NO End Date Time:  Jan/3/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	myalgia	Feb/6/2021 14:00	NO End Date Time:  Feb/7/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Nephrolithiasis]
4.	Start Date Time:	Jan/1/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/3/2021 UNK:UNK
6.	Toxicity Grade:	4

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12262253**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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Idiopathic]</p>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021130108]

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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:	Feb/6/2021 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/7/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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

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	[ ]

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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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	[ ]

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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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:	//

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

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:** 12262253

**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/25/2021
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:** 12262253

**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 :	//
----	---------------------------------	----

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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-04-2021 12:27:16 (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.

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

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

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

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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Item	Date	User	Comment
Form	Oct-16-2020 18:01:25 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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Item	Date	User	Comment
Form	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
1	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
2	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
3	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
4	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
5	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
6	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
7	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
8	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Comments

**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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Item	Date	User	Comment
9	Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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Item	Date	User	Comment
Form	Feb-05-2021 16:51:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Cristiano Zerbini	Approved	Mar-04-2021 12:27:16 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-26-2021 12:04:16 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

**Affidavit:**

N/A

Cristiano Zerbini	Approved	Feb-12-2021 16:49:09 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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.

(b) (6)	N/A	Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Jan-23-2021 09:23:34 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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.

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-16-2020 18:00:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 18:00:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> STAGE 3 COHORT S	Initial Entry



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12262253

**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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*1. Consent Was:*

Date	Location	User	Value	Reason
Oct-16-2020 18:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Cons ent Obtained  Oct/16/2020	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12262253

**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-16-2020 17:59:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12262253	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-16-2020 17:59:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1953	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-16-2020 18:00:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-16-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

18:00:32 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	HISPANIC OR LAT INO(A) OR OF SPA NISH ORIGIN	
---	--	------------------	--	--

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

Date	Location	User	Value	Reason
Oct-16-2020 18:00:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-16-2020 18:01:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/16/2020	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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-16-2020 18:01:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/16/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-16-2020 18:01:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-16-2020 18:01:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262253**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Oct-16-2020 18:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical History</b> systemic ar terial hyper <b>term:</b> tension <b>Start Date:</b> UNK/UNK /2005 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-16-2020 18:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 18:02:19 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> systemic arterial hyp ertension	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires				
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**1.a Start Date:**

Date	Location	User	Value	Reason
Oct-16-2020 18:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Oct-16-2020 18:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Oct-16-2020 18:02:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Line/M 2 H Number: Medical history Term: vasectom y Start Date: UNK/U NK/1985	New Information

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<b>Ongoing:</b> NO <b>End Date:</b>  UNK/ UNK/ 1985	
Oct-16-2020 18:02:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> vasectomy <b>Start Date:</b> UNK/ UNK/1 985 <b>Ongoing:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-16-2020 18:02:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 18:02:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> vasectomy	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Oct-16-2020 18:02:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1985	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Oct-16-2020 18:02:50 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:	New Information

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires			UNK/UNK/198 5	
Oct-16-2020 18:02:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*L.c*

Date	Location	User	Value	Reason
Oct-16-2020 18:03:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 3 <b>Number:</b> <b>Medical Hi</b> pre-diabet <b>story Term</b> es mellitu : s <b>Start Date:</b> UNK/UN K/2015 <b>Ongoing:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-16-2020 18:03:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 18:03:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> pre-diabetes mellitus	Initial Entry

***1.c Start Date:***

Date	Location	User	Value	Reason
Oct-16-2020 18:03:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.c Ongoing:***

Date	Location	User	Value	Reason
Oct-16-2020 18:03:28 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires

*1.d*

Date	Location	User	Value	Reason
Oct-21-2020 14:12:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 4</b> <b>umber:</b> <b>Medical His</b> obesity <b>tory Term:</b> <b>Start Date:</b> UNK/U NK/201 5 <b>Ongoing:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 14:12:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 14:12:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> obesity	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Oct-21-2020 14:12:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Oct-21-2020 14:12:30 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires

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

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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-16-2020 18:03:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV P OSITIVE	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 100.5	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 173.7	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 33.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 36.5	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Temperatu C  
re Unit:  
Temperatu FORE  
re Location HEAD  
::

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-19-2020 11:01:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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-16-2020 18:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-16-2020 18:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 270154	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Oct-17-2020 11:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-17-2020 11:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-17-2020 11:23:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-17-2020 11:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-17-2020 11:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-17-2020 11:23:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BR77X D: W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-17-2020 11:23:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR77XW	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Oct-17-2020 11:23:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BRT5L</b> : B	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-17-2020 11:23:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRT5LB	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-17-2020 11:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BRT5L</b> : C	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-17-2020 11:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRT5LC	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-17-2020 11:06:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-17-2020 11:06:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-17-2020 11:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-17-2020 11:06:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-17-2020 11:06:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/16/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-17-2020 11:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR77X <b>D:</b> P	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-17-2020 11:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR77XP	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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-16-2020 18:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-16-2020 18:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-16-2020 18:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-16-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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

18:04:36  
(UTC-03:00) City  
of Buenos Aires

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

Oct/16/2020 13:51

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-16-2020 18:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-16-2020 18:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Oct-16-2020 18:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

Oct-16-2020 18:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

Date	Location	User	Value	Reason
Oct-16-2020 18:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262253

**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-16-2020 18:04:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-04-2020 17:44:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262253

**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-04-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-04-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> <b>Temperature Core Unit:</b> <b>Temperature Fore Location:</b> <b>1</b> <b>D</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-04-2020 17:44:31 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires				
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**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-04-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> 36.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-04-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-04-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-05-2020 07:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-05-2020 07:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-05-2020 07:23:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 07:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Nov-05-2020 07:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Nov/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 07:23:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BR78F : S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 07:23:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR78FS	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262253

**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-04-2020 17:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-04-2020 17:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-04-2020 17:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-04-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262253

**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

17:45:07  
(UTC-03:00) City  
of Buenos Aires

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

Nov/4/2020 12:10

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-04-2020 17:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-04-2020 17:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Nov-04-2020 17:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Nov-04-2020 17:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

Date	Location	User	Value	Reason
Nov-04-2020 17:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-04-2020 16:19:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/4/2020	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-04-2020 17:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-04-2020 17:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-04-2020 17:04:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 17:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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: 12262253 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:54

				are entered. Please review and correct as appropriate.
Dec-04-2020 17:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-04-2020 17:04:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BRGTB : T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 17:04:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRGTBT	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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: 12262253 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:54

Dec-04-2020 17:04:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BSF1D : B	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 17:04:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSF1DB	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-04-2020 17:04:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BSF1D : C	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 17:04:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSF1DC	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

Date	Location	User	Value	Reason
Feb-11-2021 10:07:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	data updated
Feb-05-2021 03:46:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued: Candidate	PDQ RQ1: Thank you for the response, please update the details once available else clarify.
Feb-04-2021 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Visit schedule for 05Fev2021. As soon as subject came to site, COV CONV page is going to be completed. Thanks.
Feb-04-2021 07:00:42 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	PDQ: Convalescent visit is missing

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

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

City of Buenos Aires				and 35+ days (41) 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 the visit and obtain the CONVA sample else clarify.
Jan-25-2021 08:19:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 5: Deleted	Per reason on swab forms "Patient outside the country".
Jan-22-2021 14:09:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

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				update as appropriate.
Jan-08-2021 17:06:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Jan-08-2021 17:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-05-2021 07:16:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-04-2021 07:41:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Data updated.

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-31-2020 06:33:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	DM: Kindly consider to update missing COVID TEST form or else clarify. Thank you.
Dec-31-2020 04:09:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Deleted	Per reason on swab forms "Patient outside the country".
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-30-2020 11:57:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidat e	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-30-2020	ACV0PFEINFP6000	auto query	Query 1: Candidat	Date of Visit is

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

11:57:16 (UTC-03:00) City of Buenos Aires		(autoquery)	e	completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-30-2020 11:57:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Dec/25/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 11:57:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**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  
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**Subject Initials:** ---

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/24/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-05-2021 16:48:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Sym ptom Resolved:  Jan/10/2021	New Information
Dec-30-2020 11:58:52	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC-03:00) City of Buenos Aires				
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**4.a**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEV ER <b>Symptom Pre sent:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
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**Form Status:** Data Complete

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de  
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**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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(b) (4)

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> YES	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Dec-30-2020	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**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

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

11:58:52 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	<b>Symp</b> NEW OR INC <b>toms:</b> REASED SH ORTNESS O F BREATH  <b>Symp</b> NO <b>tom P</b> <b>resen</b> <b>t:</b>
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL	Initial Entry

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
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**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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(b) (4)

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

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Sympt NO  
om Pr  
esent:

**4.e Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW LOSS <b>oms:</b> OF TASTE OR SMELL <b>Sympt</b> NO <b>om Pre</b> <b>sent:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**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:** ---

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**4.f Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TAS TE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR IN <b>oms:</b> CREASED S ORE THRO AT <b>Sympt</b> NO <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Site No:** 1226

**Subject No:** 12262253

**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.g Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARR HEA <b>Symptom P NO</b> <b>resent:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form Version:** 10-Dec-2020 02:29

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
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**Form Status:** Data Complete

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

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

**4.h Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMIT ING <b>Symptom P NO</b> <b>resent:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**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.i Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 11:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-30-2020 11:59:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> increased bo <b>oms -</b> dy temperat <b>Other:</b> ure (37.3C)	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-30-2020 11:59:24 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> increased body temper ature (37.3C)	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

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**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

of Buenos Aires

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - 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. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - 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

Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5. Device Type:**

Date	Location	User	Value	Reason
Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Comments/Findings/Details:**

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - 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

Date	Location	User	Value	Reason
Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Jan-04-2021 07:41:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**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
Dec-30-2020 11:59:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-30-2020 11:59:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-08-2021 17:06:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-08-2021 17:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Sample Collected?" is No, but

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**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

				Barcodes are present on the page.
Jan-08-2021 17:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Jan-08-2021 17:05:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 17:05:18 (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-08-2021 17:05:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Jan/8/2021	New Information
Dec-30-2020 11:59:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**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

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

Date	Location	User	Value	Reason
Dec-30-2020 11:59:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Patient outside the co untry	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-08-2021 17:06:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP993 : J	Transcription Error (DELETED)
Jan-08-2021 17:05:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP993 : J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-08-2021 17:06:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP993J	Transcription Error (DELETED)
Jan-08-2021	ACV0PFEINFP6000	auto query	Query 1: Closed	Close Auto

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**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

17:06:34 (UTC-03:00) City of Buenos Aires		(autoquery)		Query
Jan-08-2021 17:05:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 7 characters in length. Please review and correct as appropriate.
Jan-08-2021 17:05:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP993J	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-30-2020 12:00:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-30-2020 12:00:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-22-2021 14:11:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Jan-22-2021 14:10:49 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

City of Buenos Aires				
Jan-22-2021 14:09:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Jan-22-2021 14:09:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Jan-22-2021 14:09:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	New Information

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

Jan-11-2021 08:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-08-2021 17:07:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Participant was out of the country
Jan-08-2021 17:07:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-08-2021 17:06:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 17:06:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 08/Jan/2021 is different from Date of Visit 25/Dec/2020.

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				Please review and update as appropriate, else clarify.
Jan-08-2021 17:06:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Jan/8/2021	New Information
Dec-30-2020 12:00:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 14:11:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Patient out of country	Initial Entry
Jan-22-2021 14:09:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	New Information

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

Dec-30-2020 12:00:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Patient outside the country	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Jan-22-2021 14:10:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample I</b> BP993 <b>D:</b> J	Subject barcode 12261876 <b>(DELETED)</b>
Jan-08-2021 17:07:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample I</b> BP993 <b>D:</b> J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-22-2021 14:10:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP993J	Subject barcode 12261876 <b>(DELETED)</b>
Jan-08-2021 17:07:17 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP993J	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

City of Buenos Aires				
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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020**Form Version:** 10-Dec-2020 02:26**Site No:** 1226**Subject No:** 12262253**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST T <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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

*1.b*

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Type of Practitioner:</b> EMERGENCY ROOM</p> <p><b>Occurrence of Visits or Contacts:</b> YES</p> <p><i>Number of Visits or Contacts:</i></p> <p>1</p>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROO M	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P</b> PRIMAR <b>ractitione</b> Y CARE <b>r:</b> PHYSICI AN <b>Occurren</b> NO <b>ce of Visit</b> <b>s or Cont</b> <b>acts:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PH YSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> URGE <b>itioner:</b> NT C ARE <b>Occurrence</b> NO <b>of Visits or</b> <b>Contacts:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P</b> TELEPH <b>ractitione</b> ONE CO <b>r:</b> NSULTA TION <b>Occurren</b> NO <b>ce of Visit</b> <b>s or Cont</b> <b>acts:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONS ULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practit</b> OT <b>ioner:</b> HE R <b>Occurrence of</b> NO <b>Visits or Conta</b> <b>cts:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Dec-30-2020 12:00:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/25/2020

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS - 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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-30-2020 12:00:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID- 19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-30-2020 12:00:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-30-2020 12:00:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

Date	Location	User	Value	Reason
Feb-05-2021 16:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 16:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-06-2021 07:56:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-06-2021 07:56:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-06-2021 07:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-06-2021 07:56:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

				are entered. Please review and correct as appropriate.
Feb-06-2021 07:56:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-06-2021 07:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR686N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-06-2021 07:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR686N	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

Feb-06-2021 07:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BSCW5</b> : F	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-06-2021 07:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCW5F	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-06-2021 07:56:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BSCW5</b> : D	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-06-2021 07:56:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCW5D	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site No:** 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12262253 **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
Dec-04-2020 16:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/4/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-04-2020 16:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-04-2020 16:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-05-2021 16:49:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/23/2021	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226 **Site Name:** (1226) CEPIC - Centro Paulista de  
Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12262253 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Feb-05-2021 16:49:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 16:49:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-05-2021 16:49:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willi ng to return for Va ccination 3 Participant is:  eligible per loc al/national reco	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226 **Site Name:** (1226) CEPIC - Centro Paulista de  
Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12262253 **Subject Initials:** ---

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

(b) (4)

			mmendations a nd confirmed t o have received only placebo at Vaccination 1/2	
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**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-05-2021 16:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER  
VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1. Consent Was:*

Date	Location	User	Value	Reason
Feb-05-2021 16:50:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Cons ent Obtained  Feb/5/2021	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING FOR 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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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Feb-06-2021 07:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-06-2021 07:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-06-2021 07:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

Feb-06-2021 07:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> collection performed during the convalesce nce visit performed on the same day	Initial Entry
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**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 17:37:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 17:37:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-05-2021 17:37:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 17:37:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				are entered. Please review and correct as appropriate.
Feb-05-2021 17:37:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Feb/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-05-2021 17:37:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BRH01 : K	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 17:37:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRH01K	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**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-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-05-2021	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**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

16:51:36 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Feb/5/2021 12:50
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12262253

**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

Feb-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry
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**9. Unit:**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-05-2021 16:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12262253

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-26-2021 12:04:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/26/2021	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12262253

**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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-27-2021 10:21:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-27-2021 10:21:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-27-2021 10:21:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-27-2021 10:21:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (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:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				are entered. Please review and correct as appropriate.
Feb-27-2021 10:21:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/26/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-27-2021 10:21:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR613 <b>D:</b> N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-27-2021 10:21:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR613N	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12262253

**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-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-26-2021	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12262253

**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

12:06:05 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Feb/26/2021 10:45
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Feb-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12262253

**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

Feb-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry
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**9. Unit:**

Date	Location	User	Value	Reason
Feb-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-26-2021 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

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**1. Category:**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-04-2021 09:12:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Closing query to FU at a later date.
Feb-25-2021 15:29:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject do not have any additional information

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				from discharge summary, other than the information already reported previously in the last FUP form.
Feb-25-2021 07:56:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Reissued: Opened	Response does not satisfy query
Feb-24-2021 16:55:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Candidate	Response does not satisfy query
Feb-17-2021 08:12:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	All the documents available were sent.
Feb-16-2021 14:31:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL_ Pls provide information from discharge summary (workup, clinical evolution,

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

imaging, lab results, treatment) in a FUP form so this information is added to the safety report. Thanks.

Feb-05-2021  
16:47:30  
(UTC-03:00) City of Buenos Aires

ACV0PFEINFP6000

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

**Data Entry:**  
Nephrolithiasis

Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/1/2021 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/3/2021 UNK:	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

UNK

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-10-2021 02:06:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	For AE Nephrolithiasis: Response to "Is the adverse event serious?"

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/</p>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1226

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

Subject No: 12262253

Subject Initials: ---

Generated By:

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

(b) (4)

			incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to st	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires			udy treatment(s), th is event is due to:	
			OTHER	
			<i>If Other, specify</i> :	
			Idiopathic	

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-05-2021	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

16:47:30 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	YES	
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 16:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-10-2021 02:06:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021130108	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> myalgia	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/6/2021 14:00	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/7/2021 UNK: UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 12:08:24 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-05-2021 16:49:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-05-2021 16:49:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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-04-2020 16:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-16-2020 18:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDO MIZED	Initial Entry
Oct-16-2020 18:01:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-30-2020 10:09:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-29-2020 15:50:23 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject entered data wrongly.

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

City of Buenos Aires				
Dec-29-2020 11:49:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	Illness edary: As per Illness edary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 25DEC2020. But corresponding COVID Illness visit not reported. Please clarify.
Dec-04-2020 16:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/4/2020	Initial Entry
Oct-16-2020 18:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)



**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1226

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

**Subject No:** 12262253

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aires				
Oct-16-2020 18:01:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

090177e196ae404a\Final\Final On: 01-Apr-2021 05:35 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1226

**Subject No:** 12262253

**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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*1. Casebook Signature*

Date	Location	User	Value	Reason
Dec-08-2020 15:29:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry