

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: 12262238

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

090177e196ae404c\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: 12262238

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: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12262238]
2.	Birth Date:	(b) (6)/1954
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae404c\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: 12262238

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: 12262238

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 _____
----	--	-------------------------

090177e196ae404c\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: 12262238

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:	[]

090177e196ae404c\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: 12262238

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:	[Hypothyroidism]
	Start Date:	UNK/UNK/1979
	Ongoing:	YES

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1226

Subject No: 12262238

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: 12262238

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:	[71.6]
3.	Unit:	kg
4.	Height:	[160.0]
5.	Unit:	cm
6.	Body Mass Index:	[28.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/16/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae404c\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: 12262238

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:	[270057]
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:** 12262238**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	[BR77WH]
5.b	Sample ID	[BRVBY4]
5.c	Sample ID	[BRVBY5]

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: 12262238

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	[BR77VF]
-----	-----------	----------

090177e196ae404c\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: 12262238

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 11:58
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

090177e196ae404c\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: 12262238

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
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

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: 12262238

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

Vital Signs Details

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

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: 12262238

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	[BR78F5]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262238

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 11:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae404c\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: 12262238 **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/8/2020
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12262238**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: Dec/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRGTF1]
5.b	Sample ID	[BSF1WB]
5.c	Sample ID	[BSF1WC]

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V4_MONTH6_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262238**Generated By:**

(b) (4)

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

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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	[]
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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	Oct/26/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1226**Subject No:** 12262238**Generated By:**

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1226) CEPIC - Centro Paulista de
Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Oct/26/2020
2.	Date of First Symptom Started:	Oct/23/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/27/2020

Symptoms

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[Headache]
5.b	Symptoms - Other Text:	[Increased body temperature (37.5 C)]
5.c	Symptoms - Other Text:	[Tiredness]
5.d	Symptoms - Other Text:	[Sneezing]
5.e	Symptoms - Other Text:	[Runny nose]

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1226

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

Subject No: 12262238

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 Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12262238

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:	[Recorded at swab pfe]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262238**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?	YES Date of Collection: Oct/26/2020
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	[BR6NV0]
-----	-----------	----------

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION

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](#)

Health Care Utilization

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO
Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[]
Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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[eCRF Audit Trail History](#)

Respiratory Treatment

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: ILLNESS DETAILS

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](#)

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: 12262238

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.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 17-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: ILLNESS DETAILS - SEVERE

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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Illness Details

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

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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category f or Lab Test	Vendor Name	Collecti on Date:	Specime n Type	Lab Result			Form Instan ce
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defi ned Identifier	Test:	Resul t:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12262238

Subject Initials: ---

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(b) (4)

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[eCRF Audit Trail History](#)

Lab Chemistry Details

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

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.b	Sponsor ID:	Not Done _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.c

Sponsor ID:	Not Done _____ []	Comments
Test:	Aspartate Aminotransferase_PX28	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.d

Sponsor ID:	Not Done _____ []	Comments
Test:	Alkaline Phosphatase_PX35	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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Site No: 1226

Subject No: 12262238

Generated By:

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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.e

Sponsor ID:	Not Done _____ []	Comments
Test:	Bilirubin_PX21	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.f

Sponsor ID:	Not Done _____ []	Comments
Test:	Blood Urea Nitrogen_PX47	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

5.g

Sponsor ID:	Not Done _____ []	Comments
Test:	Creatinine_PX48	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1226

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

Subject No: 12262238

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.	Not Done	Not Done	Not Done	Not Done	<table border="1"> <thead> <tr> <th data-bbox="886 716 1081 867">Sponsor-Defined Identifier</th> <th data-bbox="1081 716 1175 867">Test:</th> <th data-bbox="1175 716 1269 867">Result:</th> </tr> </thead> <tbody> <tr> <td data-bbox="886 867 1081 1005">Not Done</td> <td data-bbox="1081 867 1175 1005">Not Done</td> <td data-bbox="1175 867 1269 1005">Not Done</td> </tr> <tr> <td data-bbox="886 1005 1081 1144">Not Done</td> <td data-bbox="1081 1005 1175 1144">Not Done</td> <td data-bbox="1175 1005 1269 1144">Not Done</td> </tr> <tr> <td data-bbox="886 1144 1081 1283">Not Done</td> <td data-bbox="1081 1144 1175 1283">Not Done</td> <td data-bbox="1175 1144 1269 1283">Not Done</td> </tr> <tr> <td data-bbox="886 1283 1081 1421">Not Done</td> <td data-bbox="1081 1283 1175 1421">Not Done</td> <td data-bbox="1175 1283 1269 1421">Not Done</td> </tr> <tr> <td data-bbox="886 1421 1081 1560">Not Done</td> <td data-bbox="1081 1421 1175 1560">Not Done</td> <td data-bbox="1175 1421 1269 1560">Not Done</td> </tr> <tr> <td data-bbox="886 1560 1081 1698">Not Done</td> <td data-bbox="1081 1560 1175 1698">Not Done</td> <td data-bbox="1175 1560 1269 1698">Not Done</td> </tr> <tr> <td data-bbox="886 1698 1081 1837">Not Done</td> <td data-bbox="1081 1698 1175 1837">Not Done</td> <td data-bbox="1175 1698 1269 1837">Not Done</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages
Sponsor-Defined Identifier	Test:	Result:																												
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category f or Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12262238

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(b) (4)

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Laboratory Data Hematology

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

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.c

Sponsor ID:	Not Done _____ []	Comments
Test:	Erythrocytes_PX3	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.d

Sponsor ID:	Not Done _____ []	Comments
Test:	Platelets_PX5	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

5.e

Sponsor ID:	Not Done _____ []	Comments
Test:	Leukocytes_PX7	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1226

Subject No: 12262238

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Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.f

Sponsor ID:	Not Done _____ []	Comments
Test:	Neutrophils_PX608	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
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Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.g	Sponsor ID:	Not Done _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.h

Sponsor ID:	Not Done _____ []	Comments
Test:	Monocytes_PX612	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.i

Sponsor ID:	Not Done _____ []	Comments
Test:	Basophils_PX610	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.j

Sponsor ID:	Not Done _____ []	Comments
Test:	Lymphocytes_PX611	
Result:	Not Done _____ []	Comments
Not Done:	Not Done _____	Comments
LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date:	Vital Signs Details			Form Instance
1.	Oct/26/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Done	136	80	

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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Vital Signs

1.	Date:	Oct/26/2020	Comments
----	-------	-------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	1	
	Systolic:	[136]	Comments
	Diastolic:	[80]	Comments
	Respiratory Rate in respirations/minute:	[15]	Comments
	Heart Rate in beats/minute:	[87]	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:04

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR

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

Subject Initials: ---

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

#	Date:	Vital Signs Details		Form Instance
1.	Oct/26/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	95.0	

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:04
Site No: 1226

Subject No: 12262238

Generated By:
(b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR

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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Vital Signs

1.	Date:	Oct/26/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[95.0]

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

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: 12262238

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.	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: OXYGENATION PARAMETERS

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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Oxygenation Parameters

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1226

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

Subject No: 12262238

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.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Concomitant Medications

1.	What is the medication identifier?	Not Done _____ []	Comments
2.	Category:	Not Done _____	Comments
3.	Concomitant Medications Pre-specified:	Not Done _____	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1226

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

Subject No: 12262238

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.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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Imaging

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/23/2020

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262238

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/23/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/23/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262238**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: Nov/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS2XWS]
5.b	Sample ID	[BS2XWT]
5.c	Sample ID	[BR60F4]

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

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:** 12262238**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

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: 12262238 **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: 12262238 **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: 12262238

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

1.	Date:	//
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Vital Signs Details

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de
Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12262238**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

Lab Urinalysis

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

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

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: 12262238

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?	

090177e196ae404c\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: 12262238

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: 12262238

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 6

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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: 12262238 **Subject Initials:** ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Informed Consent - Asymptomatic Surveillance

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

Header Text: C4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de
Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12262238**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de
Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12262238**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

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: 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: 12262238

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

090177e196ae404c\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: 12262238

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/22/2021
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: 12262238

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

090177e196ae404c\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: 12262238

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: 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: 12262238

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	Pain at local injection	Oct/16/2020 20:00	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Edema at injection site	Oct/16/2020 20:00	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Redness at injection site	Oct/16/2020 20:00	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	(Left) axillary lymph node enlargement	Oct/16/2020 20:00	NO End Date Time: Oct/25/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Pain at injection site	Nov/4/2020 20:00	NO End Date Time:	Repeating Pages

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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: 12262238

Subject Initials: ---

Generated By:

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

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#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
					Nov/8/2020 UN K:UNK	

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: 12262238

Subject Initials: ---

Generated By:

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

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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)	[Pain at local injection]
4.	Start Date Time:	Oct/16/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	2

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

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

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Header Text: C4591001

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Site No: 1226

Subject No: 12262238

Generated By:

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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	[]

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1226

Subject No: 12262238

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

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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)	[Edema at injection site]
4.	Start Date Time:	Oct/16/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	2

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Header Text: C4591001

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Site No: 1226

Subject No: 12262238

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

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

Generated By:

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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	[]

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Header Text: C4591001

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Site No: 1226

Subject No: 12262238

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Redness at injection site]
4.	Start Date Time:	Oct/16/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	2

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Header Text: C4591001

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Site No: 1226

Subject No: 12262238

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

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

Generated By:

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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: ---

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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	[]

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Subject No: 12262238

Generated By:

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[(Left) axillary lymph node enlargement]
4.	Start Date Time:	Oct/16/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/25/2020 UNK:UNK
6.	Toxicity Grade:	2

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Subject No: 12262238

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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: ---

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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

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Subject No: 12262238

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Form Status: Data Complete, Locked, Frozen

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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	[]

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Subject No: 12262238

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Form: ADVERSE EVENT REPORT

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain at injection site]
4.	Start Date Time:	Nov/4/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/8/2020 UNK:UNK
6.	Toxicity Grade:	1

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Header Text: C4591001

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Subject No: 12262238

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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Subject Initials: ---

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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

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

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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: ---

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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	[]

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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: 12262238

Subject Initials: ---

Generated By:

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1226

Subject No: 12262238

Generated By:

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Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

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Medication Error

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

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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: 12262238

Subject Initials: ---

Generated By:

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

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Subject Initials: ---

Generated By:

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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:	//

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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: 12262238

Subject Initials: ---

Generated By:

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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Subject Initials: ---

Generated By:

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Concomitant Medications

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

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Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

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

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Subject Initials: ---

Generated By:

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

Generated By:

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Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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Radiation Treatment

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

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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: 12262238

Subject Initials: ---

Generated By:

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT
- Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit:
UNPLANNED_BOOSTER_CONTACT
- Unscheduled

Form: BOOSTER DOSE TRIGGER FORM

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By: (b) (4)

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

Booster Dose Trigger Form

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	
----	--	--

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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

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Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/23/2021
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: 12262238

Generated By:

(b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

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

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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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:	[]

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: 12262238

Subject Initials: ---

Generated By:

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Subject Status

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

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1226) CEPIC - Centro Paulista de
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Subject Initials: ---

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

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Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1226) CEPIC - Centro Paulista de
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Subject Initials: ---

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

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Cristiano Zerbini	Approved	Feb-12-2021 16:48:05 (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.

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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Form	Oct-17-2020 09:03:12 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de
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Form	Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
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Form Version: 06-Jul-2020 21:54

Site No: 1226

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Form: MICROBIOLOGY SPECIMEN - Comments

Form Status: Data Complete, Frozen, Verified

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1	Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: C4591001

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Subject No: 12262238

Generated By:

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Form: MICROBIOLOGY SPECIMEN - Comments

Form Status: Data Complete, Frozen, Verified

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5	Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

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7	Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

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Form: MICROBIOLOGY SPECIMEN - Comments

Form Status: Data Complete, Frozen, Verified

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8	Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: C4591001

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Form: MICROBIOLOGY SPECIMEN - Comments

Form Status: Data Complete, Frozen, Verified

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9	Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

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Subject No: 12262238

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Form: RESPIRATORY TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de
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Form Status: Data Complete, Frozen, Verified

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2	Oct-26-2020 17:21:12 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

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Site No: 1226

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(b) (4)

Form: ILLNESS DETAILS - SEVERE - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de
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Form	Oct-26-2020 17:22:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Done

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Site No: 1226

Subject No: 12262238

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Form: ILLNESS DETAILS - SEVERE - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de
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Visit: POT_COVID_ILL 1 -
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Form: ILLNESS DETAILS - SEVERE - Comments

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Site No: 1226

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Generated By:

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Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de
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Form	Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Done

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Generated By:

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(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2.a	Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	
2.a	Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2.a	Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	
2.a	Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2.a	Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	
2.a	Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2.a	Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	
2.a	Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: OXYGENATION PARAMETERS - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-26-2020 17:23:59 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: OXYGENATION PARAMETERS - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-26-2020 17:23:59 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: OXYGENATION PARAMETERS - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-26-2020 17:23:59 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: OXYGENATION PARAMETERS - Comments

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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Item	Date	User	Comment
3	Oct-26-2020 17:23:59 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - Comments

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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Item	Date	User	Comment
1	Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - Comments

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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Item	Date	User	Comment
4	Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - Comments

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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Item	Date	User	Comment
6	Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
Form	Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
1	Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
2	Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
3	Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
4	Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) (b) (4)	Not Done

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: 12262238

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	Feb-12-2021 16:48:05 (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-01-2021 09:39:58 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Jan-23-2021 09:21:31 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae404c\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: 12262238

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

Affidavit:

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

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form: 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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-17-2020 09:02:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-17-2020 09:02:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae404c\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: 12262238

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Oct-17-2020 09:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Cons ent Obtained Oct/16/2020	Initial Entry

090177e196ae404c\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: 12262238

Generated By:

(b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Oct-17-2020 09:02:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12262238	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-17-2020 09:02:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1954	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-17-2020 09:02:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-17-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

09:02:49 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	HISPANIC OR LAT INO(A) OR OF SPA NISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Oct-17-2020 09:02:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae404c\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: 12262238

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-17-2020 09:03:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-17-2020 09:03:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-17-2020 09:03:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-17-2020 09:03:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae404c\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:** 12262238**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](#)*I.a*

Date	Location	User	Value	Reason
Oct-17-2020 09:05:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 1 umber: Medical His Hypothy tory Term: roidism Start Date: UNK/U NK/197 9 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-17-2020 09:05:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-17-2020 09:05:34 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypothyroidism	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: 12262238

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-17-2020 09:05:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1979	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-17-2020 09:05:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1226

Subject No: 12262238

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-17-2020 09:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV P OSITIVE	Initial Entry

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 71.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 160.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.3	Initial Entry

090177e196ae404c\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: 12262238

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-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae404c\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: 12262238

Generated By:

(b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-17-2020 09:06:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-17-2020 09:06:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 270057	Initial Entry

090177e196ae404c\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: 12262238

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 11:00:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-17-2020 11:00:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-17-2020 11:00:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-17-2020 11:00:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404c\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: 12262238

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 11:00:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-17-2020 11:00:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR77W D: H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-17-2020 11:00:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR77WH	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-17-2020 11:00:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRVBY D: 4	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-17-2020 11:00:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVBY4	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-17-2020 11:01:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRVBY D: 5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-17-2020 11:01:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVBY5	Initial Entry

090177e196ae404c\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: 12262238

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 10:56:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-17-2020 10:56:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-17-2020 10:56:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-17-2020 10:56:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404c\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: 12262238

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 10:56:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-17-2020 10:56:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR77V D: F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-17-2020 10:56:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR77VF	Initial Entry

090177e196ae404c\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: 12262238

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-17-2020 09:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-17-2020 09:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-17-2020 09:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-17-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae404c\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: 12262238

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

09:07:16
(UTC-03:00) City
of Buenos Aires

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

Oct/16/2020 11:58

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-17-2020 09:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-17-2020 09:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-17-2020 09:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae404c\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: 12262238

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-17-2020 09:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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-17-2020 09:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-17-2020 09:07:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

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 16:01:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

090177e196ae404c\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: 12262238

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 16:01:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-04-2020 16:01:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location: Unit: 1 36.4 C FORE HEA D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-04-2020 16:01:51 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.a Temperature:

Date	Location	User	Value	Reason
Nov-04-2020 16:01:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-04-2020 16:01:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-04-2020 16:01:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

6.a Sponsor ID:

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae404c\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: 12262238

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 07:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-05-2020 07:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-05-2020 07:20:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 07:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404c\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: 12262238

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 07:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Nov/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 07:20:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR78F : 5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 07:20:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR78F5	Initial Entry

090177e196ae404c\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: 12262238

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 16:03:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-04-2020 16:03:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-04-2020 16:03:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-04-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae404c\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: 12262238

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

16:03:04
(UTC-03:00) City
of Buenos Aires

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

Nov/4/2020 11:18

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-04-2020 16:03:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

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

7. Route:

Date	Location	User	Value	Reason
Nov-04-2020 16:03:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-04-2020 16:03:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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 16:03:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae404c\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: 12262238

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-08-2020 17:13:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/2020	Initial Entry

090177e196ae404c\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: 12262238 **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-09-2020 08:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-09-2020 08:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-09-2020 08:33:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-09-2020 08:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404c\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: 12262238 Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Dec-09-2020 08:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-09-2020 08:33:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRGTF D: 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-09-2020 08:33:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRGTF1	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae404c\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: 12262238 Subject Initials: ---

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

Dec-09-2020 08:34:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSF1W D: B	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Dec-09-2020 08:34:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSF1WB	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-09-2020 08:34:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSF1W D: C	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-09-2020 08:34:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSF1WC	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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
Oct-26-2020 17:20:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-26-2020 17:14:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-26-2020 17:14:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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Site No: 1226

Subject No: 12262238

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
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Subject Initials: ---

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				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-26-2020 17:14:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-26-2020 17:14:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/26/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/23/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 16:04:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO Date of Last Sym ptom Resolved: Oct/27/2020	New Information
Oct-26-2020 17:17:04	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

(UTC-03:00) City
of Buenos Aires

4.a

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt YES om Pr esent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREA SED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

17:17:04 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Symptom NEW OR INCREASED SHORTNES S OF BREA TH Symptom NO Present:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom P YES resent:	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D MUSCLE PAIN	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

			Symp tom P resent :	
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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NEW OR INCREA SED MUSCLE PAI N	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sympt NEW LOS oms: S OF TAST E OR SME LL	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

			Sympt NO om Pr esent:	
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4.f Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW LOSS OF TA STE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symp NEW OR I toms: NCREASE D SORE T HROAT	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

			Symp YES tom P resent :	
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4.g Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NEW OR INCREA SED SORE THROA T	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Symptoms DIAR : RHEA Symptom NO Present:	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms VOMI : TING Symptom NO Present:	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-26-2020 17:17:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-26-2020 17:18:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Headache Other: che	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-26-2020 17:18:16 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

of Buenos Aires

5.b

Date	Location	User	Value	Reason
Oct-26-2020 17:18:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt Increased b oms - ody temper Other: ature (37.5 C)	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-26-2020 17:18:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Increased body temp erature (37.5 C)	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 17:19:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Tired Other: ness	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Tiredness	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-26-2020 17:19:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Symptoms - Sneez Other: ing	Initial Entry

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sneezing	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-26-2020 17:19:34 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Symptoms Runny - Other: nose	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

of Buenos Aires

5.e Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Runny nose	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - 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. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - 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

Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-26-2020 17:19:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262238**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de
Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-26-2020 17:20:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-26-2020 17:20:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-26-2020 17:20:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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

Oct-26-2020 17:20:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Recorded at swab pf e	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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
Oct-26-2020 17:20:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-26-2020 17:20:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-26-2020 17:20:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 17:20:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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

				are entered. Please review and correct as appropriate.
Oct-26-2020 17:20:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Oct/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-26-2020 17:20:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR6NV D: 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 17:20:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR6NV0	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 15:59**Site No:** 1226**Subject No:** 12262238**Generated By:**

(b) (4)

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

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Type of Pra SPE ctitioner: CIAL IST Occurrence NO of Visits or Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - 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

1.b

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P EMER ractitione GENC r: Y ROO M Occurren NO ce of Visit s or Conta cts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY RO OM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of PRIMA Practitio RY CAR ner: E PHYSI CIAN Occurre NO nce of Vi sits or C ontacts:	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URG ENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPH ONE CO	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - 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

of Buenos Aires			ner: NSULTA TION	
			Occurre nce of Vi sits or C ontacts:	
			NO	

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: TELEPHONE CON SULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Type of Pract itioner: OT HE R	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

**Occurrence of NO
f Visits or Co
ntacts:**

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Oct-26-2020 17:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-26-2020 17:21:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: RESPIRATORY TREATMENT - 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

Oct-26-2020 17:21:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry
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5. Start Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 17:21:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: ILLNESS DETAILS - 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. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-26-2020 17:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 17:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 17-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: ILLNESS DETAILS - SEVERE - 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. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-26-2020 17:22:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 17-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: ILLNESS DETAILS - SEVERE - 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

Oct-26-2020 17:22:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

(UTC-03:00) City
of Buenos Aires

5.a Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test: Not Done Result: Not Done Not Done: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
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Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

5.b LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

5.c LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:58

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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of Buenos Aires

5.d LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

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Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires				
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5.e LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

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Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

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Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1226

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(b) (4)

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5.g Sponsor ID:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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of Buenos Aires

5.g LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de
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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
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3. Collection Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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(UTC-03:00) City
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5.a Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

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Subject Initials: ---

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(b) (4)

Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5.b

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
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5.b Result:

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Date	Location	User	Value	Reason
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of Buenos Aires

5.b LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

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Site No: 1226

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(b) (4)

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(b) (4)

of Buenos Aires

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Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

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Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

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Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

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5.f Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

5.f LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

5.g LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

of Buenos Aires

5.h LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e Lab Normal Not Range: Don e	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

5.i Not Done:

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

17:22:27
(UTC-03:00) City
of Buenos Aires

(b) (4), (b) (6) Not Done

5.i LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi Not ned Identifie Don r: e Test:: Not Don e Result:: Not Don e Not Done:: Not Don e	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

			Lab Normal Not Range: Don e	
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

5.j LNMT

Date	Location	User	Value	Reason
Oct-26-2020 17:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: VITAL SIGNS - COVID - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 17:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry
Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-26-2020 17:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Do ne Systolic:: 136 Diastolic:: 80	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

			Respiratory Rate in respirations/minute: Heart Rate in beats/minute:	
Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Systolic:: Diastolic:: Respiratory Rate in respirations/minute: Heart Rate in beats/minute:	Initial Entry
Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Respiratory Rate in respirations/minute	Not Done
Heart Rate in beats/minute	Not Done

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-26-2020 17:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 136	Initial Entry
Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-26-2020 17:22:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

(UTC-03:00) City
of Buenos Aires

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-26-2020 17:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 80	Initial Entry
Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-26-2020 17:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry
Oct-26-2020 17:23:03 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: VITAL SIGNS - COVID - 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

of Buenos Aires				
Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-26-2020 17:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 87	Initial Entry
Oct-26-2020 17:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Initial Entry
Oct-26-2020 17:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:04

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-26-2020 17:23:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:23:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-26-2020 17:23:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identif 1 ier:: Oxygen Satur 95. ation: 0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-26-2020 17:23:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:04

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR - 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

Oct-26-2020 17:23:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 95.0	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: OXYGENATION PARAMETERS - 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 Time of Assessment:

Date	Location	User	Value	Reason
Oct-26-2020 17:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-26-2020 17:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-26-2020 17:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 17:24:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: IMAGING - 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: ---

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

Form: IMAGING - 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

Oct-26-2020 17:24:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<u>Data Entry:</u> Not Done	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/23/2020

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262238

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
Nov-24-2020 09:02:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/23/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-24-2020 09:02:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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: ---

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1. Data Origin

Date	Location	User	Value	Reason
Nov-24-2020 09:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-24-2020 09:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-24-2020 09:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-24-2020 09:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however no barcodes

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Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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
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				are entered. Please review and correct as appropriate.
Nov-24-2020 09:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Nov/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-24-2020 09:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BS2XW D: S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 09:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2XWS	Initial Entry

5.b

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12262238

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
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Subject Initials: ---

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Nov-24-2020 09:02:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BS2XW D: T	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 09:02:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2XWT	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-24-2020 09:02:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR60F D: 4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 09:02:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR60F4	Initial Entry

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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: 12262238 **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-08-2020 17:14:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-08-2020 17:14:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-08-2020 17:14:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae404c\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: 12262238

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-01-2021 09:39:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

090177e196ae404c\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: 12262238 **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-01-2021 09:40:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 09:40:04 (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-01-2021 09:40:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willi ng to return for Va ccination 3 Participant is: eligible and N OT confirmed t	Initial Entry

090177e196ae404c\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: 12262238 **Subject Initials:** ---

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

(b) (4)

			o have received only placebo at Vaccination 1/2	
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262238

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: ---

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Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (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: 12262238

Subject Initials: ---

Generated By:

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(b) (4)

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Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	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: 12262238

Subject Initials: ---

Generated By:

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(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Pain at local injection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020 20:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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Header Text: C4591001

Visit: Logs - Unscheduled

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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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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: 12262238

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
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:28:21 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

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Header Text: C4591001

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Site No: 1226

Subject No: 12262238

Generated By:

(b) (4)

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Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Edema at injection s ite	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020 20:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae404c\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: 12262238

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
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:29:16 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

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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: 12262238

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
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 17:33:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Redness at injection site	Transcription Error
Oct-26-2020 17:30:06	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Redness at injection	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-03:00) City of Buenos Aires			site	
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

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Header Text: C4591001

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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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Header Text: C4591001

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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

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

Date	Location	User	Value	Reason
Oct-26-2020 17:30:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

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Subject No: 12262238

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: (Left) axillary lymph node enlargement	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020 20:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/25/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

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Visit: Logs - Unscheduled

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

Subject No: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae404c\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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Subject No: 12262238

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
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:31:11 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

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Subject Initials: ---

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Subject No: 12262238

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
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pain at injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)

Header Text: C4591001

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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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 20:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/8/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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Subject Initials: ---

Generated By:

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(b) (4)

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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Header Text: C4591001

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Subject No: 12262238

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
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 09:33:12 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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of Buenos Aires

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-01-2021 09:40:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/23/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-01-2021 09:40:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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: 12262238

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-08-2020 17:14:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-17-2020 09:06:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDO MIZED	Initial Entry
Oct-17-2020 09:03:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-08-2020 17:14:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/8/2020	Initial Entry
Oct-17-2020 09:06:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry

090177e196ae404c\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: 12262238

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-17-2020 09:03:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry
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Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262238

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 15:27:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae404c\Final\Final On: 01-Apr-2021 05:35 (GMT)