

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

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

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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

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Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/12/2020
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Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12261137]
2.	Birth Date:	(b) (6)/1967
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

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(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: ---

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[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/12/2020
2.	Erroneous Visit	

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Visit: V1_DAY1_VAX1_L

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Site No: 1226

Subject No: 12261137

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: ---

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

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

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1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

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

Exclusion Criteria

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

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00

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Subject No: 12261137

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

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2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00

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Subject No: 12261137

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01

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Site No: 1226

Subject No: 12261137

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.l	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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	Aug/12/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1226

Subject No: 12261137

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: ---

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[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/12/2020
2.	Weight:	[97.3]
3.	Unit:	kg
4.	Height:	[173.5]
5.	Unit:	cm
6.	Body Mass Index:	[32.3]

Vital Signs Details

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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 :	Aug/12/2020
2.	Randomization Number:	[47218]
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: 12261137

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: Aug/12/2020
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	[BP5HGB]
5.b	Sample ID	[BP5HG9]
5.c	Sample ID	[BP5HG8]
5.d	Sample ID	[BLCTJ1]
5.e	Sample ID	[BLCTJ0]

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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:** 12261137**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: Aug/12/2020
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	[BP5HC8]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

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:	Aug/12/2020 12:28
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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12261137

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	YES - REACTOGENICITY E-DIARY 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: 12261137

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

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Date of Visit

1.	Date of Visit	Sep/3/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1226

Subject No: 12261137

Generated By:

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Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

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 Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/18/2020
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

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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(b) (4)

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/3/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

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: Sep/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9DTG]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 09:30
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

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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

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Generated By:

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(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12261137 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12261137 **Subject Initials:** ---

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

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12261137 **Subject Initials:** ---

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

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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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:** 12261137**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/2/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVYVC]
5.b	Sample ID	[BLC0RR]
5.c	Sample ID	[BLC0RS]

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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	Jan/11/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021**Form Version:** 10-Dec-2020 02:29**Site No:** 1226**Subject No:** 12261137**Generated By:**

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**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](#)**Signs and Symptoms**

1.	Date of Assessment:	Jan/11/2021
2.	Date of First Symptom Started:	Jan/6/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/8/2021

Symptoms

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

4.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.	Symptoms - Other Text:	[]

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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: 12261137

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.	Jan/7/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:54

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN

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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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Jan/7/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings /Details:	[]
9.	Trade Name Other, Specify:	[NALT Unknown]

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

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_SELF
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV63164]
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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: ---

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[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26
Site No: 1226

Form Status: Data Complete, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de
Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261137

Subject Initials: ---

Generated By:
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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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

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#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatm ent	Treatm ent	Start D ate	Form Instanc e
1.						Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: RESPIRATORY TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

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Respiratory Treatment

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12261137

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?	YES Respiratory Illness Diagnosis: [COVID-19] Date of Diagnosis: Jan/7/2021
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: 12261137

Subject Initials: ---

Generated By:

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

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Illness Details

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

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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Lab Chemistry Details

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

Lab Result

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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(b) (4)

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261137

Subject Initials: ---

Generated By:

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261137

Subject Initials: ---

Generated By:

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

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Vital Signs

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

Vital Signs Details

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date:	Vital Signs Details		Form Instance
1.	Jan/11/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	98.0	

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 30-Jul-2020 21:28

Site No: 1226

Subject No: 12261137

Generated By:

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Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Status: Data Complete, Frozen, Verified

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

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Vital Signs

1.	Date:	Jan/11/2021
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Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[98.0]

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1226

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

Subject No: 12261137

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.				Repeating Pages

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: OXYGENATION PARAMETERS

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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Oxygenation Parameters

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

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (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: 12261137

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.						Repeating Pages

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

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

Subject Initials: ---

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

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Concomitant Medications

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

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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: 12261137

Subject Initials: ---

Generated By:

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Imaging

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

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/19/2021

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

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	Feb/19/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/19/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12261137**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de
Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSCWTR]
5.b	Sample ID	[BSCWTS]
5.c	Sample ID	[BRK6ZR]

Header Text: C4591001

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

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

Site No: 1226

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

Subject No: 12261137

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 - 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: 12261137 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: C4591001

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

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

Site No: 1226

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

Subject No: 12261137

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

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	Not Applicable _____ //	Comments
2.	Phase of Disposition:	Not Applicable _____	Comments
3.	Status:	Not Applicable _____	Comments
4.	Specify Status:	Not Applicable _____ []	Comments

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: 12261137 **Subject Initials:** ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (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:** 12261137**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 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: 12261137

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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

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: 12261137

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?	

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1226

Subject No: 12261137

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: 12261137

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: 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: 12261137

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	Feb/2/2021
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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/19/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/19/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Feb/19/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[As V101 and COV CONV occurred on the same day, electronic sample tracking is recorded at cov conv form]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRK6ZD]
-----	-----------	----------

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/19/2021 14:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/12/2021
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261137**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: Mar/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRGZ4P]
-----	-----------	----------

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/12/2021 09:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Disposition - Treatment

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

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: 12261137

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	Right forearm fracture	Sep/20/2020 14:00	NO End Date Time: Sep/29/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Bicycle fall	Sep/20/2020 UNK:UNK	NO End Date Time: Sep/20/2020 UNK:UNK	Repeating Pages

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right forearm fracture]
4.	Start Date Time:	Sep/20/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/29/2020 UNK:UNK
6.	Toxicity Grade:	3

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020384860]

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

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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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

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

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [accidental cause]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

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

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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Medication Error

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

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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: 12261137

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.						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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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Concomitant Medications

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

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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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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Concomitant Medications

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

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

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Radiation Treatment

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

#	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: 12261137

Subject Initials: ---

Generated By:

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/3/2021
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: 12261137

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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090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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

Death Details

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

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: 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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Cristiano Zerbini	Approved	Mar-15-2021 16:37:03 (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.

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Aug-14-2020 12:17:06 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	
Form	Aug-12-2020 17:20:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - Comments

Form Version: 15-Sep-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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
Form	Oct-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP - 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-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP - 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
2	Oct-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

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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Item	Date	User	Comment
3	Oct-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP - 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-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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Item	Date	User	Comment
Form	Feb-19-2021 16:36:27 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Cristiano Zerbini	Approved	Mar-15-2021 16:37:03 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Mar-12-2021 12:07:32 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Mar-01-2021 10:02:24 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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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-19-2021 16:33:04 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Feb-10-2021 17:40:46 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6) [Redacted]	N/A	Jan-11-2021 16:19:57 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Oct-28-2020 17:26:44 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

(b) (6)	N/A	Oct-28-2020 13:16:33 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Oct-27-2020 16:46:03 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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	Oct-26-2020 08:20:28 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Oct-10-2020 07:55:58 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Oct-03-2020 10:13:54 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Sep-14-2020 16:55:43 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

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.

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

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
Aug-12-2020 16:47:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 16:47:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

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
Aug-12-2020 16:47:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Cons ent Obtained Aug/12/2020	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261137

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-12-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12261137	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-12-2020 16:47:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1967	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-12-2020 16:47:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-12-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

16:47:53 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	HISPANIC OR LAT INO(A) OR OF SP ANISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-12-2020 16:47:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-12-2020 16:48:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/12/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Incl 1 usio n N um ber:</p> <p>Crit Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)</p> <p>Crit YES</p> <p>erio n m et?:</p>	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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1.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<u>Data Entry:</u> 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<u>Data Entry:</u> Male or female parti cipants between the ages of 18 and 55 ye ars, inclusive, 65 an d 85 years, inclusive , or 18 and 85 years, inclusive, at random ization (dependent u	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

pon study stage)

1.a Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Incl 2 usio n N umb er:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			<p>Crit Participants w erio ho are willing n D and able to co escr mply with all iptio scheduled visi n: ts, vaccinatio n plan, labora tory tests, life style consider ations, and ot her study proc edures</p> <p>Crit YES erio n m et?:</p> <p>Crit IN02A00 erio n ID : (F or P fizer use only):</p>	
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

1.b Inclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to c omply with all sche duled visits, vaccina tion plan, laboratory tests, lifestyle consi derations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 3 usio n N um ber: Crit Healthy partic erio ipants who ar n D e determined escr by medical hi ipti story, physica on: l examination, and clinical ju dgment of the investigator to be eligible for inclusion in th e study	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

1.c Inclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

1.c Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, physical examinatio n, and clinical judg ment of the investig ator to be eligible fo r inclusion in the stu dy	Initial Entry

1.c Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 4 usio n N umb er: Crit Capable of gi erio ving personal n D signed inform escr ed consent, w iptio hich includes n: compliance w ith the require ments and res trictions listed in the ICD an d in this proto col	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

			<p>Crit YES</p> <p>erio</p> <p>n m</p> <p>et?:</p> <p>Crit IN04A00</p> <p>erio</p> <p>n ID</p> <p>: (F</p> <p>or P</p> <p>fizer</p> <p>use</p> <p>only</p> <p>):</p>	
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090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

1.d Inclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving p ersonal signed infor med consent, which includes compliance with the requiremen ts and restrictions lis ted in the ICD and i n this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Excl 1 usio n N um ber: Crit Other medical erio or psychiatric n D condition incl. escr recent (within ipti past year) or a on: ctive suicidal ideation/beha vior/lab abnor mality that ma y increase the risk of study p articipation	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

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

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2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Other medical or ps ychiatric condition i ncl. recent (within p ast year) or active su	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

icidal ideation/behavior/lab abnormality that may increase the risk of study participation

2.a Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 2 usion Num ber:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

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

			<p>Crite Known infec rion tion with hu Desc man immuno ription deficiency vi on: rus (HIV), he patitis C viru s (HCV), or hepatitis B vi rus (HBV)</p> <p>Crite NO rion met? : Crite EX02A00 rion ID: (For Pfize r use only) :</p>	
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090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: EX02A00	Initial Entry
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2.c

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Excl 3 usio n N umb er: Crit History of sev erio ere adverse re n De action associa scri ted with a vac ptio cine and/or se n: vere allergic r eaction (eg, a naphylaxis) to any compone nt of the stud y intervention (s) Crit NO erio n m et?:	Initial Entry

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Header Text: C4591001

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Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

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

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			or P	
			fizer	
			use	
			only	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261137

Subject Initials: ---

Generated By:

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(b) (4)

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe ad verse reaction associ ated with a vaccine and/or severe allergi c reaction (eg, anap hylaxis) to any com ponent of the study i ntervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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Header Text: C4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Exclusi 4 on Nu mber: Criteria Receipt of on Des medicatio criptio ns intende n: d to preve nt COVID -19 Criteria NO on met ?: Criteria EX04A00 on ID: (For Pf izer use only):	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medicati ons intended to prev ent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.e

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Excl 8 usio n N umb er:</p> <p>Crit Immunocomp erio romised indiv n De iduals with k scri nown or susp ptio ected immun n: odeficiency, a s determined by history an d/or laborator y/physical ex amination</p> <p>Crit NO erio n m et?:</p>	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

			Crit EX08A00 erio n ID : (Fo r Pfi zer use only):	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromis ed individuals with known or suspected immunodeficiency, as determined by his tory and/or laborator y/physical examinati on	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 12261137

Subject Initials: ---

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(b) (4)

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Excl 10 usio n N umb er: Crit Bleeding diat erio hesis or condi n De tion associate scri d with prolon ptio ged bleeding t n: hat would, in the opinion of the investigat or, contraindi cate intramus cular injectio n	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

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Subject No: 12261137

Generated By:

(b) (4)

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

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Subject Initials: ---

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			Crit NO erion m et?: Crit EX10A00 erion ID : (F or P fizer use only):	
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

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Subject Initials: ---

Generated By:

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

(b) (4)

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis o r condition associate d with prolonged ble eding that would, in the opinion of the in vestigator, contraind icate intramuscular i njection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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Header Text: C4591001

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

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (For Pfizer use only): EX11A00	Initial Entry

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Header Text: C4591001

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

Generated By:

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(b) (4)

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pre gnant or breastfeedi ng	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

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Subject Initials: ---

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(b) (4)

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2.h

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: (For Pfizer use only): EX12A00	Initial Entry

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Header Text: C4591001

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(b) (4)

2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

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Subject Initials: ---

Generated By:

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(b) (4)

of Buenos Aires

2.i

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number:</p> <p>Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p>Criterion met?</p> <p>Criterion ID: (For Pfizer use only): EX13A01</p>	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

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Subject Initials: ---

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(b) (4)

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: C4591001

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Subject Initials: ---

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(b) (4)

Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry
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2.j

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 15 usio n N umb er: Crit Receipt of blo erio od/plasma pr n De oducts or im scri munoglobulin ptio , from 60 day n: s before study intervention a dministration or planned re ceipt through out the study Crit NO erio n m et?:	Initial Entry

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Header Text: C4591001

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Subject No: 12261137

Generated By:

(b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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

			Crit EX14A01 erio n ID : (F or P fizer use only):	
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090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1226

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

Generated By:

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

(b) (4)

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX14A01	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

2.k

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Excl 16</p> <p>usio</p> <p>n Nu</p> <p>mbe</p> <p>r:</p> <p>Crit Participation</p> <p>erio in other studi</p> <p>n De es involving</p> <p>scrip study interve</p> <p>tion: ntion within</p> <p>28 days prior</p> <p>to study entr</p> <p>y and/or duri</p> <p>ng study part</p> <p>icipation</p> <p>Crit NO</p> <p>erio</p> <p>n me</p> <p>t?:</p>	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

			Crit EX15A01 erio n ID : (Fo r Pfi zer u se on ly):	
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090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

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

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.1

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclu 17 sion Num ber: Crite Previous par tion ticipation in Descr other studie iptio s involving n: study interv ention conta ining lipid n anoparticles Crite NO tion met?:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			Crite EX16A01 rion I D: (F or Pfi zer u se onl y):	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Previous participati on in other studies i nvolving study inter vention containing l ipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry
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2.m

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 22 lusi on Nu mbe r: Crit Investigator s erio ite staff or Pfi n D zer employee escr s directly inv ipti olved in the c on: onduct of the study, site staf f otherwise su pervised by th e investigator, and their resp ective family members	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			<p>Crit NO erio n m et?: Crit EX21A01 erio n I D: (For Pfiz er u se o nly) :</p>	
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090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staf f or Pfizer employe es directly involved in the conduct of th e study, site staff ot herwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-12-2020 16:48:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-12-2020 16:49:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Aug/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-12-2020 16:49:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-12-2020 16:49:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: COMPLETED	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Aug-14-2020 12:17:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 1 umber: Medical His Obesity tory Term: Start Date: UNK/U NK/200 0 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 12:17:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:17:22 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Obesity	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

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
Aug-14-2020 12:17:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: UNK/UNK/2000	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 12:17:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Aug/12/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 97.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 173.5	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 36.7	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Temperature Unit:
Temperature Location: HEAD

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

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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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-12-2020 16:52:03 (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 Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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: ---

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-12-2020 16:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/12/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 47218	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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: ---

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1. Data Origin

Date	Location	User	Value	Reason
Aug-12-2020 17:18:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-12-2020 17:18:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-12-2020 17:18:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 17:18:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

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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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Aug-12-2020 17:18:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/12/2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 17:25:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Closed	Response satisfies query
Aug-14-2020 10:18:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-14-2020 06:38:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Opened	GPD CLIN: Please confirm if all sample IDs are provided for blood draw for immunogenicity as only 3 of the expected 5

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

sample IDs/aliquots are reported. Please provide comment for reason or update all sample IDs as applicable.

5.a

Date	Location	User	Value	Reason
Aug-12-2020 17:18:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5HG : B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 17:18:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5HGB	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-12-2020 17:18:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5HG	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	:	9	
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 17:18:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5HG9	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-12-2020 17:19:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5HG : 8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 17:19:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5HG8	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-14-2020 10:18:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCTJ1	Initial Entry
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5.d Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 10:18:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCTJ1	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-14-2020 10:18:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCTJ0	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 10:18:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCTJ0	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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
Aug-12-2020 17:19:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-12-2020 17:19:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-12-2020 17:19:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 17:19:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

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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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Aug-12-2020 17:19:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-12-2020 17:19:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP5HC : 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 17:19:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5HC8	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

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
Aug-12-2020 16:53:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-12-2020 16:53:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-12-2020 16:53:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-12-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

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

16:53:42
(UTC-03:00) City
of Buenos Aires

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

Aug/12/2020 12:28

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-12-2020 16:53:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-12-2020 16:53:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-12-2020 16:53:42 (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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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-12-2020 16:53:42 (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
Aug-12-2020 16:53:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (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: 12261137

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
Aug-12-2020 16:53:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES - REACTOGE NICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 12:22:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sys N temic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

2.b Symptom:				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry
2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
2.c				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

2.c Symptom:				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry
2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
2.d				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI L LS Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

2.d Symptom:				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry
2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
2.e				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

2.e Symptom:				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry
2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
2.f				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARR HEA Were fever YES or systemic Ongo symptoms p g? resent on th e last day th NO e Subject Di ary was com pleted?: Stop Dat e: Au g/ 18 /2 02 0	Initial Entry

2.f Symptom:				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry
2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/18/2020	Initial Entry
2.g				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN Were fever o NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	Initial Entry

2.g Symptom:				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry
2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
2.h				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever or NO systemic sym ptoms presen t on the last d ay the Subjec t Diary was c ompleted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 12:31:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Re RE action:: D NE SS	Initial Entry

			Were injection site reactions present on the last day the Subject Diary was completed?:	
--	--	--	---	--

5.a Injection Site Reaction:				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b				
Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTIO N SI TE Were injection NO site reactions present on the last day the Su bject Diary wa s completed?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 12:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261137

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
Sep-03-2020 12:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 12:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature 36.6 : Temperature C Unit: Temperature FORE Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 12:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261137

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

2.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 12:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 12:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 12:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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
Sep-03-2020 12:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 12:33:27 (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
Sep-03-2020 16:56:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 12:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Sep-03-2020 12:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:56:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP9DT : G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:56:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP9DTG	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 12:34:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 12:34:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 12:34:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-03-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

12:34:38 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Sep/3/2020 09:30	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 12:34:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 12:34:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 12:34:38 (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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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-03-2020 12:34:38 (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
Sep-03-2020 12:34:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (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: 12261137

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
Oct-03-2020 10:13:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261137**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sy N stemic symptom O s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

2.b Symptom:				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: FATIGUE	Initial Entry
2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
2.c				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: HE AD AC HE Were fever or s NO ystemic sympto ms present on t he last day the S ubject Diary wa s completed?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI L LS Were fever or sy N stemic symptom O s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

2.d Symptom:				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: CHILLS	Initial Entry
2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
2.e				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary w as completed?:	Initial Entry

2.e Symptom:				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: VOMITING	Initial Entry
2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
2.f				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: DI AR RH EA Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN Were fever o NO r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?:	Initial Entry

2.g Symptom:				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry
2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
2.h				
Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever o NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Injection Site R RE action:: D NE SS	Initial Entry

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTI ON S ITE Were injectio NO n site reaction s present on t he last day the Subject Diary was complete d?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: PAIN AT INJECTIO N SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-03-2020 10:14:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

Header Text: C4591001

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

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

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

Subject No: 12261137 **Subject Initials:** ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-03-2020 11:46:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-03-2020 11:46:05 (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-03-2020 11:46:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-03-2020 11:46:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12261137 Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Oct-03-2020 11:46:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-03-2020 11:46:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPVYV D: C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-03-2020 11:46:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVYVC	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12261137 Subject Initials: ---

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

Oct-03-2020 11:46:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BLCOR : R	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-03-2020 11:46:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCORR	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-03-2020 11:46:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BLCOR : S	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-03-2020 11:46:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCORS	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 07:01:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Closed as Convalescent Visit completed.
Feb-17-2021 03:09:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Candidate	PDQ RQ1: Thank you for the response, please confirm the date scheduled in query response and requesting to respond to query once data available. Else clarify.
Feb-16-2021 15:00:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Visit is schedule for the next few days. As soon as visit occur it will be updated. Thanks

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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

Feb-16-2021 03:20:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35 days (36) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Jan-12-2021 15:39:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-12-2021 06:27:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-11-2021 16:19:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-11-2021 16:19:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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

				review and update as appropriate.
Jan-11-2021 16:19:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-11-2021 16:19:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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. Date of Assessment:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/11/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/6/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO Date of Last Symptom Resolved: Jan/8/2021	Initial Entry

4.a

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Pr NO esent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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			D COUGH Sympt YES om Pr esent:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (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
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sym NEW OR IN ptom CREASED s: SHORTNES S OF BREA TH	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

					Symptom Present: NO
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4.c Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (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
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

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Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D MUSCLE PAIN Symp YES tom P resent :	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREA SED MUSCLE PAI N	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW LOS oms: S OF TAST E OR SME LL Sympt NO om Pr esent:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TA STE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D SORE T HROAT Symp YES tom P resent :	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

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Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREA SED SORE THROA T	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms DIAR : RHEA Symptom NO Present:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

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Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms VOMI : TING Symptom NO Present:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:29

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 16:22:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:54

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - 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
Jan-11-2021 16:26:40 (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 Jan/11/2021

Form Version: 06-Jul-2020 21:54

Site No: 1226

Subject No: 12261137

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
Jan-11-2021 16:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/7/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-11-2021 16:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: SWABBED MATE RIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-11-2021 16:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-11-2021	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:54

Site No: 1226

Subject No: 12261137

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

16:26:40
(UTC-03:00) City
of Buenos Aires

(autocalc)

SEVERE ACUTE RES
P SYNDROME CORO
NAVIRUS 2

5. Device Type:

Date	Location	User	Value	Reason
Jan-11-2021 16:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-11-2021 16:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-11-2021 16:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Initial Entry

9. Trade Name Other, Specify:

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

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Site No: 1226

Subject No: 12261137

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
Jan-11-2021 16:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NALT Unknown	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 15:39:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 15:39:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 15:39:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-12-2021 15:39:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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

				are entered. Please review and correct as appropriate.
Jan-12-2021 15:39:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Collectio n: Jan/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 15:39:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample I CV6316 D: 4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 15:39:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: CV63164	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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
Jan-11-2021 16:26:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 16:26:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-11-2021 16:26:58 (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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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Jan-11-2021 16:26:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: self-swab	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

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

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I.a

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	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
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:26
Site No: 1226

Subject No: 12261137

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
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMER GENC Y ROOM Occurrence of Visits or Contacts: NO	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

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
Jan-11-2021 16:27:55 (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
Jan-11-2021 16:27:55 (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
Jan-11-2021 16:27:55 (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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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pra URG ctitioner: ENT CARE Occurrence NO of Visits or Contacts:	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of TELEPH Practitio ONE CO	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

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 NO	
			nence of Vi	
			sits or C	
			ontacts:	

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (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
Jan-11-2021 16:27:55 (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
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Type of Pract OT itioner: HE R	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Jan-11-2021 16:27:55 (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
Jan-11-2021 16:27:55 (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
Jan-11-2021 16:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12261137

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
Jan-11-2021 16:29:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 16:29:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COVID-19 Date of Diagnosis: Jan/7/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-11-2021 16:29:07 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12261137

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

of Buenos Aires

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 30-Jul-2020 21:28

Site No: 1226

Subject No: 12261137

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
Jan-11-2021 16:32:37 (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 Jan/11/2021

Form Version: 30-Jul-2020 21:28

Site No: 1226

Subject No: 12261137

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

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1. Date:

Date	Location	User	Value	Reason
Jan-11-2021 16:32:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-11-2021 16:32:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identif 1 ier:: Oxygen Satur 98. ation: 0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-11-2021 16:32:37 (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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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/11/2021

Form Version: 30-Jul-2020 21:28

Site No: 1226

Subject No: 12261137

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

Jan-11-2021 16:32:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 98.0	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/19/2021

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-19-2021 16:34:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/19/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-19-2021 16:34:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-22-2021 09:24:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-22-2021 09:24:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 09:25:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 09:24:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Feb-22-2021 09:24:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collectio n: Feb/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 09:25:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample I BSCWT D: R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 09:25:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BSCWTR	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Feb-22-2021 09:25:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSCWT D: S	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 09:25:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSCWTS	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 09:25:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRK6Z D: R	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 09:25:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRK6ZR	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

Site No: 1226

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

Subject No: 12261137

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-05-2020 16:52:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-05-2020 16:52:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-05-2020 16:52:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-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: 12261137

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-28-2020 17:04:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-28-2020 13:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-28-2020 13:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-27-2020 15:02:47 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Refer to CRF CR section 8.55. DISPOSITION

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				SCREENING (DISP SCR)/TREATMENT (DISP TRT)/FOLLOW UP (DISP FUP) on how to complete this form. Thank you.
Oct-27-2020 11:59:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Another DM made the following request in "Right Forearm Fracture" AE: "If test was NOT performed or available, please submit FU report as well so it is reflected in the narrative". For that reason this FUP was opened.
Oct-27-2020 10:54:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Subject has completed only till visit 3 and ongoing in the study. If this is correct, please remove all data entered in this CRF (Disposition follow up CRF). Else clarify.
Oct-26-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

08:20:28
(UTC-03:00)
City of Buenos
Aires

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

Oct/2/2020

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Oct-28-2020 13:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-26-2020 08:20:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Not Applicable	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-28-2020 13:20:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-28-2020 13:20:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-28-2020 13:20:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry:	Transcription Error
Oct-28-2020 13:16:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Oct-28-2020 13:16:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

				subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-28-2020 13:16:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [redacted] [redacted]	Data Entry: ADVERSE EVENT	Transcription Error
Oct-26-2020 13:27:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [redacted] [redacted]	Query 1: Closed	Response satisfies query
Oct-26-2020 08:32:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [redacted] [redacted]	Query 1: Answered	Status provided due solicitation and query about the "Right Forearm Fracture".
Oct-26-2020 08:20:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is COMPLETED but "Specify Status" is Provided.

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-26-2020 08:20:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: COMPLETED	Initial Entry
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4. Specify Status:

Date	Location	User	Value	Reason
Oct-28-2020 13:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Not Applicable	Initial Entry
Oct-28-2020 13:20:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry:	Transcription Error
Oct-26-2020 08:20:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Since the AE "Right forearm fracture" had an accidental cause, covid test was not necessary.	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (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: 12261137

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-19-2021 16:33:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (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: 12261137 **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-19-2021 16:33:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/n ational recommend ations and confirm ed to have received only placebo at Va ccination 1/2	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 18:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 10:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Feb-22-2021 08:40:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing SWAB PFE and SAMP TRK forms or else clarify. Thank you.
Feb-19-2021 16:34:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/19/2021	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-19-2021 16:36:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consen t Obtained Feb/19/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-19-2021 16:36:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/19/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-19-2021 16:36:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-19-2021 16:36:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-22-2021 10:32:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-22-2021 10:32:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 10:32:24 (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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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Feb-22-2021 10:32:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: As V101 and COV CONV occurred on t he same day, eletron ic sample tracking is recorded at cov con v form	Initial Entry
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090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

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
Feb-22-2021 10:32:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-22-2021 10:32:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 10:32:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 10:32:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Feb-22-2021 10:32:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 10:32:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRK6Z D: D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 10:32:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRK6ZD	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-19-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

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

16:37:01
(UTC-03:00) City
of Buenos Aires

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

Feb/19/2021 14:30

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
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9. Unit:

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 16:37:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

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
Mar-12-2021 12:07:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Mar/12/2021	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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
Mar-12-2021 16:25:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-12-2021 16:25:41 (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
Mar-12-2021 16:25:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 16:25:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Mar-12-2021 16:25:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 16:25:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRGZ4 D: P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 16:25:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRGZ4P	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

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
Mar-12-2021 12:09:20 (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
Mar-12-2021 12:09:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-12-2021 12:09:20 (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
Mar-12-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

12:09:20 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Mar/12/2021 09:40
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5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-12-2021 12:09:20 (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
Mar-12-2021 12:09:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-12-2021 12:09:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261137

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

Mar-12-2021 12:09:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
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9. Unit:

Date	Location	User	Value	Reason
Mar-12-2021 12:09:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-12-2021 12:09:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 12:09:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261137

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (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: 12261137

Subject Initials: ---

Generated By:

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(b) (4)

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Date	Location	User	Value	Reason
Oct-06-2020 12:06:05 (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, Verified

Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (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 11:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Thank you!
Oct-26-2020 08:22:28 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Done.

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1226

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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(b) (4)

City of Buenos Aires				
Oct-24-2020 21:39:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued: Opened	If test was NOT performed or available, please submit FU report as well so it is reflected in the narrative.
Oct-23-2020 15:04:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Since the AE was an accidental cause, covid test was not necessary. Narrative "the bike crash was totally accidental, causing the forearm fracture."
Oct-22-2020 14:28:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	COVID testing has not been recorded in the SAE submitted to safety. If test performed = YES, please provide FU form with results. If NOT test performed or available, please submit FU form as well so it is reflected in the narrative.
Oct-09-2020 13:02:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1226

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Subject No: 12261137

Subject Initials: ---

Generated By:

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Oct-09-2020 12:53:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Oct-09-2020 09:29:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The form was sent in 08/Oct/2020.
Oct-09-2020 07:48:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	SAE RECON 1:Per latest SAE listing, the date of birth is still missing/blank. Please confirm if a follow up AEM form was sent for AER 2020384860.
Oct-08-2020 11:19:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The subject fractured the right forearm on 20/Sep /2020, and immobilized the area on the same day. On 28/Sep/2020 he was hospitalized to have a surgery done on this forearm.
Oct-07-2020 14:45:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	In the SDB case narrative records the subject was seen in ER/ortho the same day and he was hospitalized only from

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

Subject No: 12261137

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Generated By:

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

(b) (4)

				28-29 Sep. If so, please verify/update dates as the event was first non-serious and then resulted in a hospitalization later.
Oct-07-2020 06:55:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	SAE RECON: Pending SDB data updated
Oct-06-2020 12:04:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	form will be updated today
Oct-06-2020 07:48:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020384860 ,the date of birth was missing in Safety database but was recorded as (b) (6)/1967 in AE CRF. Please confirm if date of birth was reported. If safety update is required, please submit a follow-up form.
Oct-03-2020 10:27:09 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right for earn frac	Initial Entry

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Header Text: C4591001

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Subject No: 12261137

Subject Initials: ---

Generated By:

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(b) (4)

Buenos Aires			ture	
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/20/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/29/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

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

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Generated By:

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(b) (4)

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-06-2020 07:42:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Oct-05-2020 15:59:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Form AE / SAE Fax Cover Sheet was sent on 02oct2020 at 18:11.
Oct-05-2020 10:47:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	SAE RECON: Right forearm fracture(Onset date:20Sep2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

				serious, downgrade the event on AE CRF
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Right forearm fracture: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	Initial Entry

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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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(b) (4)

			on?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Subject No: 12261137

Subject Initials: ---

Generated By:

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(b) (4)

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-07-2020 05:16:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-06-2020 12:06:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE Fall added
Oct-05-2020 06:38:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As per CRF Completion Guidelines Section 8.46.2.2. Fall as well as the Injury due to the fall need to be recorded as two separate Adverse Event. Please consider updating another AE

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Subject Initials: ---

Generated By:

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(b) (4)

				with the term Fall, Thank you.
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> fall bike	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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(b) (4)

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-03-2020 10:27:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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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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Oct-06-2020 07:38:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 2020384860	Initial Entry
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Header Text: C4591001

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1. Category:

Date	Location	User	Value	Reason
Oct-06-2020 12:06:05 (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-06-2020 12:06:05 (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-06-2020 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bicycle fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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(b) (4)

Oct-06-2020 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/20/2020 UNK:U NK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-06-2020 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/20/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-06-2020 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	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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Date	Location	User	Value	Reason
Oct-06-2020 12:06:05 (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-06-2020 12:06:05 (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-06-2020 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> accidental cause	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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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: 12261137

Subject Initials: ---

Generated By:

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(b) (4)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-06-2020 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-06-2020 12:06:05 (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-06-2020 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 12:06:05 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESO LVED	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (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, Verified

Site No: 1226

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

Subject No: 12261137

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-06-2020 12:06:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO	Initial Entry

090177e196ae405\Final\Final On: 01-Apr-2021 05:38 (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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-19-2021 16:33:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-19-2021 16:33:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261137

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
Oct-28-2020 13:20:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Transcription Error
Oct-28-2020 13:16:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Transcription Error
Oct-26-2020 08:20:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COMPLETED	Initial Entry
Oct-05-2020 16:52:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-12-2020 16:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RAND OMIZED	Initial Entry
Aug-12-2020 16:49:06 (UTC-03:00) City	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-28-2020 13:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Transcription Error
Oct-28-2020 13:20:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Transcription Error
Oct-28-2020 13:16:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Transcription Error
Oct-26-2020 08:20:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Initial Entry
Oct-05-2020 16:52:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Initial Entry
Aug-12-2020 16:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/12/2020	Initial Entry

090177e196ae405f\Final\Final On: 01-Apr-2021 05:38 (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: 12261137

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-12-2020 16:49:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/12/2020	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: 12261137

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
Sep-14-2020 16:49:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry