

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

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

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/14/2020
----	--------------	--

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12261713]
2.	Birth Date:	(b) (6)/1983
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**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	Sep/14/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

**Inclusion Criteria**

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

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

**Exclusion Criteria**

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

2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

2.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
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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

2 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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/14/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

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

[Form Comments](#)

**Medical History Details**

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/14/2020
2.	Weight:	[95.4]
3.	Unit:	kg
4.	Height:	[185.3]
5.	Unit:	cm
6.	Body Mass Index:	[27.8]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/14/2020
2.	Randomization Number:	[89451]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
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	[BP7K0W]
5.b	Sample ID	[BP7K0V]
5.c	Sample ID	[BP7K0T]
5.d	Sample ID	[BLBPS1]
5.e	Sample ID	[BLBPS0]

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
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	[BPWV0L]
-----	-----------	----------

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**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/14/2020 13:36
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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/5/2020
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/5/2020
----	-------	------------

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/5/2020
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	[BPVZ0M]
-----	-----------	----------

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/5/2020 13:06
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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR78CR]
5.b	Sample ID	[BS2VCN]
5.c	Sample ID	[BS2VCP]

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** DATE OF VISIT - ILLNESS ONSET

**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:** 12261713

**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 Illness Visit**

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 28-Mar-2021 02:35

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Signs and Symptoms**

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
----	------------------------	-----

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF Visit

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** HEALTH CARE UTILIZATION

**Form Version:** 28-Mar-2021 02:23

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Health Care Utilization**

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

**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?	
----	--	--

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Illness Details**

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

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

**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	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**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 Version:** 15-Sep-2020 21:55

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB  
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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 28-Mar-2021 02:28

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Vital Signs**

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

**Vital Signs Details**

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

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION

**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](#)

**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:** 12261713

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

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



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRH011]
5.b	Sample ID	[BSCW5V]
5.c	Sample ID	[BSCW5T]

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRH021]
-----	-----------	----------

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/5/2021 12:58
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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/26/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR613L]
-----	-----------	----------

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/26/2021 10:55
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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1226

**Subject No:** 12261713

**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:** 12261713

**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:** 12261713

**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:** 12261713

**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:** 12261713

**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:** 12261713

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Pain at injection site	Feb/5/2021 17:58	NO End Date Time: Feb/6/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Exposure During Pregnancy	Feb/1/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain at injection site]
4.	Start Date Time:	Feb/5/2021 17:58
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/6/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**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

[Back to Form](#)  
[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)	[Exposure During Pregnancy]	
4.	Start Date Time:	Feb/1/2021 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	<a href="#">Comments</a>
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	

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**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

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**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	[ ]

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**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/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

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



**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

**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-16-2021 11:46:01 (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.

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-15-2020 07:56:29 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-05-2021 15:54:01 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Mar-10-2021 07:37:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

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-16-2021 11:46:01 (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 10:29:26 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Cristiano Zerbini	Approved	Mar-10-2021 14:50:20 (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-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261713**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54**Affidavit:**

N/A

Cristiano Zerbini	Approved	Mar-03-2021 13:40:10 (UTC-03:00) City of Buenos Aires	BOOK	Signed
-------------------	----------	---	------	--------

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-26-2021 13:22:23 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Cristiano Zerbini	Approved	Feb-12-2021 10:15:00 (UTC-03:00) City of Buenos Aires	BOOK	Signed
-------------------	----------	---	------	--------

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-05-2021 15:44:19 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Cristiano Zerbini	Approved	Nov-07-2020 09:25:25 (UTC-03:00) City of Buenos Aires	BOOK	Signed
-------------------	----------	---	------	--------

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Affidavit:**

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

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

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



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Sep-15-2020 07:54:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:54:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261713

**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:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-15-2020 07:54:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> OBTAINED Date Written Consent Obtained  Sep/14/2020	Initial Entry

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261713

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
Sep-15-2020 07:54:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12261713	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-15-2020 07:54:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1983	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**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
Sep-15-2020 07:55:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criterion Description:</b> 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) <b>Criterion met?:</b> <b>Criterion ID: (For Pfizer use only):</b>	Initial Entry

*1.a Inclusion Number:*

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

*1.a Criterion Description:*

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

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry
---	-----------------	------------------	--	---------------

*1.a Criterion met?*

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN01A00	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criteria:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

***1.b Inclusion Number:***

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

***1.b Criterion Description:***

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

***1.b Criterion met?***

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN02A00	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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

Buenos Aires

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

**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:** IN03A00  
**Use Only:** (For Pfizer use only):

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

**I.c Inclusion Number:**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**I.c Criterion Description:**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

**I.c Criterion met?**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN03A00	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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

Buenos Aires

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

**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:** IN04A00  
**Use Only:** (For Pfizer use only):

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

**I.d Inclusion Number:**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

**I.d Criterion Description:**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

**I.d Criterion met?**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN04A00	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclu 1	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 21-Aug-2020 02:50  
**Site No:** 1226

**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 No:** 12261713  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 13:54

		(b) (4), (b) (6)	<p><b>Exclusion Number:</b></p> <p><b>Criterion Description:</b> 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</p> <p><b>Criterion ID:</b> EX01A00</p> <p><b>Drug Name:</b> (F or Pfizer only)</p>
--	--	------------------	--

**2.a Exclusion Number:**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Criterion Description:**

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.a Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusi 2 on Nu mber: <b>Criteria</b> Known infection with <b>on Desc</b> human immunodefici <b>ription:</b> ency virus (HIV), hep atitis C virus (HCV), or hepatitis B virus (HBV) <b>Criteria</b> NO <b>on met</b> ?: <b>Criteria</b> EX02A00 <b>on ID: (</b> <b>For Pfi</b> <b>zer use</b> <b>only):</b>	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.b Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclu 3 sion N	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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><b>umbe</b></p> <p><b>r:</b></p> <p><b>Criterion Description:</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</p> <p><b>Criterion ID:</b> NO</p> <p><b>Criterion ID:</b> EX03A00</p> <p><b>Criterion ID:</b> (For Pfizer use only):</p>	
--	--	--	---	--

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.c Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg , anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion 4	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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

		(b) (4), (b) (6)	<p><b>Number:</b></p> <p><b>Criterion D description:</b> Receipt of medications intended to prevent COVID-19</p> <p><b>Criterion m NO et?:</b></p> <p><b>Criterion I EX04A00 D: (For Pfizer use only):</b></p>	
--	--	------------------	--	--

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.d Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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><b>Criteria</b> Immunocompromised <b>on Description:</b> individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p><b>Criteria met?:</b> NO</p> <p><b>Criteria ID:</b> EX08A00 <b>(For Pfizer use only):</b></p>	
--	--	--	--	--

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.e Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclus 10	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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

		(b) (4), (b) (6)	<p><b>ion Nu mber:</b></p> <p><b>Criterion Description:</b> Bleeding diathesis or condition associated with prolonged bleeding time that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID:</b> EX10A00</p> <p><b>Criterion ID:</b> (For Pfizer use only):</p>	
--	--	------------------	--	--

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.f Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Nu 11	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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

		(b) (4), (b) (6)	<p><b>Number:</b></p> <p><b>Criterion Description:</b> Women who are pregnant or breastfeeding</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID:</b> EX11A00 (For Pfizer use only):</p>	
--	--	------------------	--	--



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.g Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: 12	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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><b>Criterion D description:</b> Previous vaccination with any coronavirus vaccine</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID: (For Pfizer use only):</b> EX12A00</p>	
--	--	--	--	--

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.h Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: 13	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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><b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID: (Formerly Pfizer use only):</b> EX13A01</p>	
--	--	--	--	--

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.i Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclus 15 ion Nu	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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

			<b>number:</b> <b>Criterion Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX14A01 <b>Use only:</b> (For Pfizer only)	
--	--	--	--	--

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.j Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX14A01	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

2.k

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation <b>Criterion met?:</b> <b>Criterion ID:</b> EX15A01 <b>(For Pfizer use only):</b>	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participation in other studies in involving study intervention with in 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusio 17	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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

Buenos Aires

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

**n Number:**

**Criterion Description:** Previous participation in other studies involving study intervention containing lipid nanoparticles

**Criterion met?:** NO

**Criterion ID: (Former Pfizer only):** EX16A01

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion 22	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1226

**Subject No:** 12261713

**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

		(b) (4), (b) (6)	<p><b>Number:</b></p> <p><b>Criterion:</b> 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</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID:</b> EX21A01</p> <p><b>For Pfizer use only:</b></p>	
--	--	------------------	--	--

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

2.m Exclusion Number:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 07:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX21A01	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-15-2020 07:56:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-15-2020 07:56:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-15-2020 07:56:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 95.4	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 185.3	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261713

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

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

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 27.8	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier: 1 : Temperature: 36.8 Temperature Unit C : Temperature Location: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (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
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.8	Initial Entry

7.a Unit:

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1226

**Subject No:** 12261713

**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

Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry
---	-----------------	---------------------	-------------------------	---------------

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-15-2020 07:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 89451	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-15-2020 11:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-15-2020 11:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-15-2020 11:42:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 11:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-15-2020 11:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-15-2020 11:42:46	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Sample ID: BP7K0W
----------------------------------	---------------------	-------------------

5.a Sample ID

Date	Location	User	Value	Reason
Sep-15-2020 11:42:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP7K0W	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-15-2020 11:43:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP7K0V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-15-2020 11:43:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP7K0V	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-15-2020 11:44:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP7K0T	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-15-2020 11:44:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP7K0T	Initial Entry

5.d

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-15-2020 11:45:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BLBPS1</b>	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-15-2020 11:45:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLBPS1	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-15-2020 11:45:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BLBPS0</b>	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-15-2020 11:45:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLBPS0	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261713**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-15-2020 11:46:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-15-2020 11:46:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-15-2020 11:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 11:46:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-15-2020 11:46:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-15-2020 11:46:21	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

(UTC-03:00) City of Buenos Aires

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

**Sample ID:** BPWV0L

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-15-2020 11:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWV0L	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261713

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020 13:36	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 08:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-15-2020 08:00:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261713

**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
Oct-05-2020 17:09:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001**Visit:** V2\_VAX2\_L**Form Version:** 15-Sep-2020 21:54**Site No:** 1226**Subject No:** 12261713**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 36.6 <b>Temperature Unit</b> C : <b>Temperature Location:</b> FOREHEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.6	Initial Entry

**2.a Unit:**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261713

**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

Oct-05-2020 17:10:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry
---	-----------------	---------------------	-------------------------	---------------

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

**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:** 12261713**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-05-2020 17:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-05-2020 17:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-05-2020 17:20:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 17:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-05-2020 17:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/5/2020	Initial Entry

**5.a**

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

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Oct-05-2020 17:20:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVZ0M	Initial Entry
--	-----------------	------------------	--	---------------

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-05-2020 17:20:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVZ0M	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261713

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020 13:06	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
---	-----------------	---------------------	----------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 17:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261713

**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
Nov-03-2020 16:59:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**Header Text:** C4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject No:** 12261713**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-03-2020 18:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-03-2020 18:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-03-2020 18:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 18:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-03-2020 18:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/3/2020	Initial Entry

**5.a**

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

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: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

Nov-03-2020 18:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR78CR	Initial Entry
---	-----------------	---------------------	--	---------------

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 18:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR78CR	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-03-2020 18:04:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS2VCN	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 18:04:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS2VCN	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-03-2020 18:04:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS2VCP	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

*5.c Sample ID*

Date	Location	User	Value	Reason
Nov-03-2020 18:04:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS2VCP	Initial Entry

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-03-2020 16:59:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-03-2020 16:59:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-03-2020 16:59:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**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
Feb-05-2021 15:44:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

**Header Text:** C4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1226**Subject No:** 12261713**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Feb-05-2021 15:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 15:44:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-05-2021 15:44:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1226

**Subject No:** 12261713

**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
Feb-05-2021 15:47:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Feb-05-2021 15:47:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtain ed  Feb/5/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-05-2021 15:54:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-05-2021 15:54:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-05-2021 15:54:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 15:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 15:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-06-2021 08:02:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-05-2021 15:54:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-05-2021 15:54:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-05-2021 15:54:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Feb/5/2021	Transcription Error
Feb-05-2021 15:54:24	ACV0PFEINFP6000	auto query	Query 1: Opened	'Sample Collected?'

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires		(autoquery)		is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-05-2021 15:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-06-2021 08:02:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRH011	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-06-2021 08:02:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRH011	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-06-2021 08:02:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSCW5V	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-06-2021 08:02:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCW5V	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-06-2021 08:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSCW5T	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-06-2021 08:02:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCW5T	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261713

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 17:46:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 17:46:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-05-2021 17:46:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 17:46:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-05-2021 17:46:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-05-2021 17:46:44	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1226

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

**Subject No:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

(UTC-03:00) City of Buenos Aires

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

**Sample ID:** BRH021

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 17:46:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRH021	Initial Entry



Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261713

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021 12:58	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
---	-----------------	---------------------	----------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 15:55:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1226

**Subject No:** 12261713

**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
Feb-26-2021 13:22:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/26/2021	Initial Entry

**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:** 12261713**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-27-2021 10:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-27-2021 10:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-27-2021 10:22:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-27-2021 10:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-27-2021 10:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/26/2021	Initial Entry

**5.a**

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

**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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Feb-27-2021 10:22:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR613L	Initial Entry
--	-----------------	------------------	--	---------------

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-27-2021 10:22:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR613L	Initial Entry

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261713

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/26/2021 10:55	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

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

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
--	-----------------	------------------	----------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:23:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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. Category:**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pain at injection site	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021 17:58	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/6/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - 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

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 13:26:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - 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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exposure During Pregnancy	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/1/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

Date	Location	User	Value	Reason
Mar-10-2021 07:37:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 18:05:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-12-2021 10:29:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Updated

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - 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

Aires				
<p>Mar-12-2021 10:29:26 (UTC-03:00) City of Buenos Aires</p>	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Participant</p>	Updated

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - 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

			y	
Mar-12-2021 10:23:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Open ed	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Pregnancy]. However subject is "Male" , Kindly confirm the AE is correctly recorded. (b) (4)
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED D If Not Related to st udy tr eatme nt(s), this e vent i s due to:  OTHER  If Ot	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261713

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

			her , s pe cif y:  P r e g n a n c y
--	--	--	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-15-2021 11:30:20	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - 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

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		query
Mar-15-2021 11:25:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Per 3 Nov EDP guidance , outcome should be recorded as UNKNOWN.
Mar-15-2021 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AE is pregnancy of the partner. The AE is still ongoing.
Mar-15-2021 08:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Exposure During Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-15-2021 08:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-15-2021 08:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	Transcription Error
Mar-15-2021 06:13:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021261857, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Per 3 Nov EDP guidance , outcome should be recorded as UNKNOWN. Please confirm and update accordingly.

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - 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

Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT R ESOLVED	Initial Entry
---	-----------------	---------------------	--	---------------

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

Date	Location	User	Value	Reason
Mar-10-2021 07:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-05-2021 15:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-05-2021 15:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261713

**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

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Nov-03-2020 16:59:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-15-2020 08:00:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-15-2020 07:56:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-03-2020 16:59:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/3/2020	Initial Entry
Sep-15-2020 08:00:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/14/2020	Initial Entry
Sep-15-2020 07:56:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

090177e196ae4059\Final\Final On: 01-Apr-2021 05:37 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail 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:** 12261713

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-06-2020 15:05:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry