

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Cohort Selection

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

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

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(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/16/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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Demography

1.	Subject ID	[12261745]
2.	Birth Date:	(b) (6)/1985
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

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(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/16/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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

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

Inclusion Criteria

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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

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

Exclusion Criteria

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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.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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

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Subject Initials: ---

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

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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

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Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/16/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]	Comments
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[allergic rhinitis]	Comments
	Start Date:	UNK/UNK/1995	Comments
	Ongoing:	YES	Comments

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1226

Subject No: 12261745

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/16/2020
2.	Weight:	[61.3]
3.	Unit:	kg
4.	Height:	[168.0]
5.	Unit:	cm
6.	Body Mass Index:	[21.7]

Vital Signs Details

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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/16/2020
2.	Randomization Number:	[90922]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP7K3S]
5.b	Sample ID	[BP7K3W]
5.c	Sample ID	[BP7K3V]
5.d	Sample ID	[BRXVT7]
5.e	Sample ID	[BRXVT6]

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP7K5J]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

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/16/2020 11:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

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(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/6/2020
2.	Erroneous Visit	

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12261745

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/6/2020
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Vital Signs Details

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
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	[BPVZ2M]
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

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/6/2020 10:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261745**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

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

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR78G4]
5.b	Sample ID	[BS2VFF]
5.c	Sample ID	[BS2VFG]

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

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Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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	[]
----	-----------	-----

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 28-Mar-2021 02:35

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

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

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:	[]
----	------------------------	-----

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12261745**Generated By:**

(b) (4)

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

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 28-Mar-2021 02:23

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION

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

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?	
----	--	--

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 06-Jul-2020 21:52

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: ILLNESS DETAILS

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

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: DATE OF VISIT - ILLNESS CONVALESCENT

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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 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:** 12261745**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	[]
----	-----------	-----

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

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

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

Subject No: 12261745 **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:	
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261745**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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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: 12261745 **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: 12261745 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: C4591001

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

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

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Vaccination

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 16:01

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 6

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

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

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

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

Subject No: 12261745 **Subject Initials:** ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -
 Unscheduled **IMMUNOGENICITY**

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

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

Subject No: 12261745 **Subject Initials:** ---

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

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[]

Header Text: C4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de
Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261745**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1226

Subject No: 12261745

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/22/2021
2.	Erroneous Visit	

Header Text: C4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Leydig cell tumor in left testicle	Sep/23/2020 UNK:UNK	NO End Date Time: Oct/7/2020 UNK :UNK	Repeating Pages

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[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)	[Leydig cell tumor in left testicle]
4.	Start Date Time:	Sep/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/7/2020 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [unknown cause]</p>

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

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?	NO
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	[2020429343]

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[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	[]

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Concomitant Medications

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Concomitant Medications

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[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?	

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT
- Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit:
UNPLANNED_BOOSTER_CONTACT
- Unscheduled

Form: BOOSTER DOSE TRIGGER FORM

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By: (b) (4)

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

Booster Dose Trigger Form

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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 :	//
----	---------------------------------	----

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature -
Unscheduled

Form: 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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[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	Feb-12-2021 10:19:20 (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.

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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
1.a	Sep-16-2020 16:46:57 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	subject do not take any corticosteroids for this condition

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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
1.a	Sep-16-2020 16:46:57 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	subject do not take any corticosteroids for this condition

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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
1.a	Sep-16-2020 16:46:57 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	subject do not take any corticosteroids for this condition

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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
1.a	Sep-16-2020 16:46:57 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	subject do not take any corticosteroids for this condition

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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[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	Feb-12-2021 10:19:20 (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	Feb-01-2021 09:26:17 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Nov-11-2020 21:56:45 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Nov-09-2020 16:59:49 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Nov-07-2020 09:38:34 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

Affidavit:

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

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-16-2020 16:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Cons ent Obtained Sep/16/2020	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12261745

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-16-2020 16:44:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12261745	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:44:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1985	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-16-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

16:45:18 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	HISPANIC OR LAT INO(A) OR OF SPA NISH ORIGIN	
---	--	------------------	--	--

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

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-16-2020 16:45:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 1 usio n N um ber: Crit Male or femal erio e participants n D between the a escr ges of 18 and ipti 55 years, inclu on: sive, 65 and 8 5 years, inclus ive, or 18 and 85 years, inclu sive, at rando mization (dep endent upon st udy stage) Crit YES erio n m et?:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Crit IN01A00
erion I
D: (For
Pfizer
use
only)
:

1.a Inclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female parti cipants between the ages of 18 and 55 ye ars, inclusive, 65 an d 85 years, inclusive , or 18 and 85 years, inclusive, at random ization (dependent u	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

pon study stage)

1.a Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 2 usio n N umb er:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			<p>Crit Participants w erio ho are willing n D and able to co escr mply with all iptio scheduled visi n: ts, vaccinatio n plan, laborat ory tests, lifes tyle considera tions, and oth er study proce dures</p> <p>Crit YES erio n m et?:</p> <p>Crit IN02A00 erio n ID : (F or P fizer use only):</p>	
--	--	--	--	--

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

1.b Inclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to c omply with all sche duled visits, vaccina tion plan, laboratory tests, lifestyle consi derations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 3 usio n N um ber: Crit Healthy partic erio ipants who ar n D e determined escr by medical hi ipti story, physical on: examination, and clinical ju dgment of the investigator to be eligible for inclusion in th e study	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

			<p>Crit YES</p> <p>erio</p> <p>n m</p> <p>et?:</p> <p>Crit IN03A00</p> <p>erio</p> <p>n ID</p> <p>: (F</p> <p>or P</p> <p>fize</p> <p>r us</p> <p>e on</p> <p>ly):</p>	
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

1.c Inclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

1.c Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, physical examinatio n, and clinical judg ment of the investig ator to be eligible fo r inclusion in the stu dy	Initial Entry

1.c Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

1.d

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 4 usio n N umb er: Crit Capable of gi erio ving personal n De signed inform scri ed consent, w ptio ich includes n: compliance w ith the require ments and res trictions listed in the ICD an d in this proto col	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

			<p>Crit YES</p> <p>erio</p> <p>n m</p> <p>et?:</p> <p>Crit IN04A00</p> <p>erio</p> <p>n ID</p> <p>: (F</p> <p>or P</p> <p>fizer</p> <p>use</p> <p>only</p> <p>):</p>	
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

1.d Inclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving p ersonal signed infor med consent, which includes compliance with the requirement s and restrictions list ed in the ICD and in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 1 usio n N um ber: Crit Other medical erio or psychiatric n D condition incl. escr recent (within ipti past year) or a on: ctive suicidal ideation/beha vior/lab abnor mality that ma y increase the risk of study p articipation	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 15-Sep-2020 21:52**Site No:** 1226**Subject No:** 12261745**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

			Crit NO erion m et?: Crit EX01A00 erion n I D: (For Pfizer use only) :	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Other medical or ps ychiatric condition i ncl. recent (within p ast year) or active su	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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

2.a Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 2 usion Num ber:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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>Crite Known infection Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)</p> <p>Crite NO</p> <p>ription met?</p> <p>:</p> <p>Crite EX02A00</p> <p>ription ID: (</p> <p>For</p> <p>Pfizer</p> <p>use</p> <p>only)</p> <p>:</p>	
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.b Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry
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2.c

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 3 usio n N umb er: Crit History of sev erio ere adverse re n De action associa scri ted with a vac ptio cine and/or se n: vere allergic r eaction (eg, a naphylaxis) to any compone nt of the stud y intervention (s) Crit NO erio n m et?:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

			Crit EX03A00 erio n ID : (F or P fizer use only):	
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Subject Initials: ---

Generated By:

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

(b) (4)

2.c Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe ad verse reaction associ ated with a vaccine and/or severe allergi c reaction (eg, anaph ylaxis) to any comp onent of the study in tervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Site No: 1226

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Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion: Receipt of on Description: medicatio criptio ns intende n: d to preve nt COVID -19 Criterion met?: NO Criterion ID: EX04A00 (For Printer use only):	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.d Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medicatio ns intended to preve nt COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.e

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Excl 8 usio n N umb er:</p> <p>Crit Immunocomp erio romised indiv n De iduals with k scri nown or susp ptio ected immun n: odeficiency, a s determined by history an d/or laborator y/physical ex amination</p> <p>Crit NO erio n m et?:</p>	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

			Crit EX08A00 erio n ID : (Fo r Pfi zer use only):	
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.e Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

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Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 10 usio n N umb er: Crit Bleeding diat erio hesis or condi n De tion associate scri d with pron ptio ged bleeding t n: hat would, in the opinion of the investigat or, contraindi cate intramus cular injectio n	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Audit Trail History

Form Version: 15-Sep-2020 21:52

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Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

			<p>Crit NO erio n m et?: Crit EX10A00 erio n ID : (F or P fizer use only):</p>	
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.f Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis o r condition associate d with prolonged ble eding that would, in the opinion of the in vestigator, contraind icate intramuscular i njection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (For Pfizer only): EX11A00	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.g Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pre gnant or breastfeedi ng	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.h

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met? : NO Criterion ID: (For Pfizer use only): EX12A00	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.h Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.i

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 13</p> <p>Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p>Criterion met? NO</p> <p>Criterion ID: EX13A01</p> <p>For Pfizer only:</p>	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.i Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry
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2.j

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 15 usio n N umb er: Crit Receipt of blo erio od/plasma pr n De oducts or im scri munoglobulin ptio , from 60 day n: s before study intervention a dministration or planned re ceipt through out the study Crit NO erio n m et?:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.j Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

2.k

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Excl 16</p> <p>usio</p> <p>n Nu</p> <p>mbe</p> <p>r:</p> <p>Crit Participation</p> <p>erio in other studi</p> <p>n De es involving</p> <p>scrip study interve</p> <p>tion: ntion within</p> <p>28 days prior</p> <p>to study entr</p> <p>y and/or duri</p> <p>ng study part</p> <p>icipation</p> <p>Crit NO</p> <p>erio</p> <p>n me</p> <p>t?:</p>	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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

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			se on	
			ly):	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.k Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.1

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclu 17 sion Num ber: Crite Previous par rion ticipation in Descr other studies iptio involving st n: udy interven tion containi ng lipid nan oparticles Crite NO rion met?:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participati on in other studies i nvolving study inter vention containing l ipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry
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2.m

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 22 lusi on Nu mbe r: Crit Investigator si erio te staff or Pfiz n D er employees escr directly invol ipti ved in the con on: duct of the stu dy, site staff o therwise supe rvised by the i nvestigator, a nd their respe ctive family members	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de
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Subject No: 12261745

Subject Initials: ---

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

2.m Exclusion Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staf f or Pfizer employe es directly involved in the conduct of th e study, site staff ot herwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-16-2020 16:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-16-2020 16:45:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-16-2020 16:45:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12261745**Generated By:**

(b) (4)

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

Date	Location	User	Value	Reason
Sep-16-2020 16:46:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical History Term: allergic rhinitis Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:46:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:46:33 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: allergic rhinitis	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires				
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1.a Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:46:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:46:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1226

Subject No: 12261745

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-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 61.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 168.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.6	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

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:: D

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:25 (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-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 16:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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-16-2020 16:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 90922	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 17:13:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 17:13:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 17:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 17:13:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Sep-16-2020 17:13:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 17:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP7K3S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP7K3S	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-16-2020 17:13:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP7K3 : W	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:13:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP7K3W	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-16-2020 17:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP7K3 : V	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP7K3V	Initial Entry

5.d

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-16-2020 17:14:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRXVT : 7	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:14:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRXVT7	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-16-2020 17:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRXVT : 6	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRXVT6	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 17:20:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 17:20:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 17:20:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 17:20:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Sep-16-2020 17:20:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 17:20:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP7K5 : J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 17:20:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP7K5J	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

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-16-2020 16:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 16:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 16:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-16-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

16:49:35
(UTC-03:00) City
of Buenos Aires

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

Sep/16/2020 11:33

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 16:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 16:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 16:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

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

Sep-16-2020 16:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-16-2020 16:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-16-2020 16:49:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

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-06-2020 12:58:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12261745

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-06-2020 12:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-06-2020 12:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 36.5 Temperature Unit: Temperature Location: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-06-2020 12:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

2.a Temperature:

Date	Location	User	Value	Reason
Oct-06-2020 12:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-06-2020 12:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-06-2020 12:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-07-2020 09:10:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-07-2020 09:10:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-07-2020 09:10:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 09:10:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-07-2020 09:10:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 09:10:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPVZ2 D: M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 09:10:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPVZ2M	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

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-06-2020 13:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-06-2020 13:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-06-2020 13:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-06-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

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

13:01:21 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Oct/6/2020 10:20	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-06-2020 13:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-06-2020 13:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-06-2020 13:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-06-2020 13:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-06-2020 13:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-04-2020 16:21:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745 **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-05-2020 08:36:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-05-2020 08:36:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-05-2020 08:36:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 08:36:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745 Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Nov-05-2020 08:36:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Nov/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 08:36:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR78G : 4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 08:36:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR78G4	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (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: 12261745 Subject Initials: ---

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

Nov-05-2020 08:36:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS2VF : F	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 08:36:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2VFF	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 08:37:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS2VF : G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 08:37:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2VFG	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

Subject No: 12261745 **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
Nov-04-2020 16:21:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-04-2020 16:21:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-04-2020 16:21:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-01-2021 09:26:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

Header Text: C4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Locked, Frozen

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

Subject No: 12261745 **Subject Initials:** ---

Generated By: (b) (4) **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-01-2021 09:26:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 09:26:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-01-2021 09:26:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willi ng to return for Va ccination 3 Participant is: eligible and N OT confirmed t	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Locked, Frozen

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

Subject No: 12261745 **Subject Initials:** ---

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

(b) (4)

			o have received only placebo at Vaccination 1/2	
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261745

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
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-13-2020 08:54:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Event term updated in SDB. Issue resolved
Nov-12-2020 09:22:14 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	for PSSR review

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				
Nov-12-2020 08:51:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	A new FUP was sent few days ago with this atualization. Please let us know if some problem with the sent happened.
Nov-12-2020 07:36:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020429343,the term was updated to 'Leydig cell tumor in left testicle' in AE CRF while recorded as Left Testicle Tumor in Safety database. Please confirm correct term.If safety update is required, please submit a follow-up form.
Nov-10-2020 16:27:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leydig cell tumor in left testicle	New Information
Oct-09-2020 11:21:16 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261745**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4)

City of Buenos Aires				
Oct-09-2020 10:24:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject is not taking any of this treatments.
Oct-07-2020 09:55:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinquery <input type="checkbox"/> any on-going systemic cytostatic agent with immunocompromising effect? Any radiotherapy?
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: left testicular tumor	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-13-2020 11:32:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 10:04:04 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	There is no on-going concomitant

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires				medication for this AE.
Nov-13-2020 03:51:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQ: any on-going anti-cancer agent, or combination to steroid for this tumor?
Nov-12-2020 13:37:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQ: any on-going anti-cancer agent, or combination to steroid for this tumor?
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-10-2020 13:31:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	resolved

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-09-2020 16:59:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	data entry correction
Nov-09-2020 16:59:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/7/2020 UN K:UNK	data entry correction
Nov-09-2020 15:59:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source document, SAE was resolved on 07Oct2020. Please verify and update, if applicable. Tks!
Nov-04-2020 16:24:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/8/2020 UN K:UNK	New Information
Oct-06-2020 13:03:44 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires				
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-05-2020 06:55:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 16:23:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE left testicular tumor: Response to "Is the adverse event

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

				serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-04-2020 16:23:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incap</p>	New Information

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

			acity? NO Is this serious event life threatening? NO Other medically important serious event NO	
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown cause	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 16:23:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 13:03:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-05-2020 06:55:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020429343	Initial Entry
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Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12261745

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-01-2021 09:26:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-01-2021 09:26:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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-04-2020 16:21:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-16-2020 16:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-16-2020 16:45:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-04-2020 16:21:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/4/2020	Initial Entry
Sep-16-2020 16:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261745

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

Sep-16-2020 16:45:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Initial Entry
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090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261745

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-06-2020 15:10:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae406d\Final\Final On: 01-Apr-2021 05:39 (GMT)