

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: C4591001	Form: MAIN INFORMED CONSENT
Visit: COHORT_SELECTION	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Site No: 1226	Subject Initials: ---
Subject No: 12261571	Generated Time (GMT): 29-Mar-2021 13:54
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/5/2020
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Header Text: C4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY
Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261571 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Demography		
1.	Subject ID	[12261571]
2.	Birth Date:	(b) (6) 1975
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

eCRF Audit Trail History

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

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00

1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00

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

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

Exclusion Criteria

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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

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Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261571
Generated By: (b) (4)

Form: DISPOSITION - SCREENING
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Sep/5/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Medical History Details

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

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Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:51
Site No: 1226
Subject No: 12261571
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/5/2020
2.	Weight:	[68.8]
3.	Unit:	kg
4.	Height:	[169.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.1]

Vital Signs Details

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

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Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1226
Subject No: 12261571
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/5/2020
2.	Randomization Number:	[82803]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTJPM]
5.b	Sample ID	[BPTJPN]
5.c	Sample ID	[BPTJPP]
5.d	Sample ID	[BPHNWK]
5.e	Sample ID	[BPHNWL]

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTJP6]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

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/5/2020 15:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Site No: 1226	Subject Initials: ---
Subject No: 12261571	Generated Time (GMT): 29-Mar-2021 13:54
Generated By: (b) (4)	

[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: 12261571

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001
Visit: V2_VAX2_L
Form Version: 15-Sep-2020 21:54
Site No: 1226
Subject No: 12261571
Generated By: (b) (4)

Form: VITAL SIGNS - TEMP
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/25/2020
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Vital Signs Details

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
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	[BP7X9X]
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

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/25/2020 09:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/26/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/26/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR60GD]
5.b	Sample ID	[BS2Y0N]
5.c	Sample ID	[BS2Y0P]

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Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

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: 12261571

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

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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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

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: 12261571

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: 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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 28-Mar-2021 02:35

Form Status: Not Started

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
Form Version: 28-Mar-2021 02:23 **Form Status:** Not Started
Site No: 1226 **Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject No: 12261571 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:54

Health Care Utilization

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

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

Subject No: 12261571 **Subject Initials:** ---

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

Illness Details

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

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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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: 12261571

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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/26/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1226

Subject No: 12261571

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:	[]

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - 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: 12261571

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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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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

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: 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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: VACCINATION

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

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?	

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1226

Subject No: 12261571

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: 12261571

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 - 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: 12261571

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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

Header Text: C4591001

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

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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Excoriations in various regions of the body	Oct/21/2020 UNK:UNK	NO End Date Time: Oct/30/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Bruises in various regions of the body	Oct/21/2020 UNK:UNK	NO End Date Time: Oct/30/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Peri-renal hematoma	Oct/21/2020 UNK:UNK	NO End Date Time: Oct/30/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Subarachnoid hemorrhage	Oct/21/2020 UNK:UNK	NO End Date Time: Oct/30/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Fracture of the fourth cervical vertebra	Oct/21/2020 UNK:UNK	NO End Date Time: Oct/30/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Cervical spinal cord contusion	Oct/21/2020 UNK:UNK	NO End Date Time: Oct/30/2020 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	hit by motorcycle	Oct/21/2020 18:00	NO End Date Time: Oct/21/2020 UNK:UNK	Repeating Pages

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Excoriations in various regions of the body]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/30/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hit by motorcycle]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

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

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

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bruises in various regions of the body]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/30/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hit by motorcycle]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

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

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

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Header Text: C4591001		Form: ADVERSE EVENT REPORT
Visit: Logs - Unscheduled		Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02		Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Site No: 1226		Subject Initials: ---
Subject No: 12261571		Generated Time (GMT): 29-Mar-2021 13:54
Generated By: (b) (4)		
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Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Peri-renal hematoma]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/30/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hit by motorcycle]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020418631]

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Header Text: C4591001		Form: ADVERSE EVENT REPORT
Visit: Logs - Unscheduled		Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02		Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Site No: 1226		Subject Initials: ---
Subject No: 12261571		Generated Time (GMT): 29-Mar-2021 13:54
Generated By: (b) (4)		
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Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Subarachnoid hemorrhage]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/30/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hit by motorcycle]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020418631]

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261571**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fracture of the fourth cervical vertebra]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/30/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hit by motorcycle]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020418631]

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261571**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cervical spinal cord contusion]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/30/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [hit by motorcycle]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020418631]

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Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1226
Subject No: 12261571
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Locked, Frozen
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:54

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[hit by motorcycle]
4.	Start Date Time:	Oct/21/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/21/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [accidental]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	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	[2020418631]

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Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

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Medication Error

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

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

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

Subject Initials: ---

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

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Concomitant Medications

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

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Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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Concomitant Medications

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

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Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

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Radiation Treatment

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

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

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

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

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: 12261571

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: 12261571

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?	
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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/10/2021
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: 12261571

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/26/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Cristiano Zerbini	Approved	Feb-12-2021 10:00:15 (UTC-03:00) City of Buenos Aires	BOOK	Signed

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.

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Sep-05-2020 16:40:27 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Cristiano Zerbini	Approved	Feb-12-2021 10:00:15 (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-11-2021 17:43:59 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Nov-30-2020 15:32:04 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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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	Nov-26-2020 16:51:45 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Nov-26-2020 16:24:02 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

(b) (6)	N/A	Nov-26-2020 12:15:10 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Cristiano Zerbini	Approved	Nov-06-2020 15:37:22 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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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.

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-05-2020 16:36:03 (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-05-2020 16:36:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/5/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-05-2020 16:35:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 12261571	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-05-2020 16:35:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) 1975	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-05-2020 16:36:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/5/2020	Initial Entry

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 21-Aug-2020 02:50
Site No: 1226
Subject No: 12261571
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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<i>I.a</i>				
Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Criteria 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) Criteria met?: Criterion ID: (For Pfizer use only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

I.a Criterion met?

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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

Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: 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: IN02A00 (For Pfizer use only):	Initial Entry

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Header Text: C4591001

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Site No: 1226

Subject No: 12261571

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

I.b Inclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

I.b Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

I.b Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: 3	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

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Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

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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>Criteria: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p>Criteria met?: YES</p> <p>Criteria ID: IN03A00 (For Pfizer use only):</p>	
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Header Text: C4591001

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Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

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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

I.c Inclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: 4	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

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Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

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

Subject Initials: ---

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

			<p>Criteria Description: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p>Criteria met?: YES</p> <p>Criteria ID: IN04A00 (For Pfizer use only):</p>	
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Header Text: C4591001

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Site No: 1226

Subject No: 12261571

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

1.d Inclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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)

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

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Generated By: (b) (4)

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

Subject Initials: ---

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			<p>Criteria on 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</p> <p>Criteria met?: NO</p> <p>Criteria ID: EX01A00 (For Pfizer use only)</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX01A00	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

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Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Buenos Aires	(b) (4), (b) (6)
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2.b

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1226

Subject No: 12261571

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.b Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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)	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1226

Subject No: 12261571

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: ---

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			Criteria met?: NO Criteria ID: (For Pfizer use only): EX03A00	
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2.c Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention (s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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)

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason

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Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19 Criterion met?: NO Criterion ID: EX04A00 (For Pfizer use only):	Initial Entry
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: C4591001

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Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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<p>Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) [redacted] (4), [redacted] (b) (6) [redacted]</p>	<p>Data Entry: 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</p>	<p>Initial Entry</p>
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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.e Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (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-05-2020 16:36:56 (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)

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

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Header Text: C4591001

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Form Status: Data Complete, Locked, Frozen, Verified

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			Criteria on met?: NO Criteria on ID: (For Pfizer use only): EX10A00	
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2.f Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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)

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (F EX11A00 or Pfizer use only):
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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

Sep-05-2020 16:36:56 (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: (EX12A00 For Pfizer use only):	Initial Entry
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (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-05-2020 16:36:56 (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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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

Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (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-05-2020 16:36:56 (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-05-2020 16:36:56 (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
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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: ---

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2.j

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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: EX14A01 For Pfizer use only):	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1226

Subject No: 12261571

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.j Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX14A01	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

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Site No: 1226

Subject No: 12261571

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: ---

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2.k				
Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

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Header Text: C4591001

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Site No: 1226

Subject No: 12261571

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: ---

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion 17 Number: Criterion Previous participation in other studies involving study intervention containing lipid nanoparticles Description: Criterion NO met?:	Initial Entry

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Header Text: C4591001

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Site No: 1226

Subject No: 12261571

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: ---

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			Criterion ID: (For Pfizer use only): EX16A01	
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2.l Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.l Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.l Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 22	Initial Entry

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Header Text: C4591001

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Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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>Criteria 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</p> <p>Criteria Met?: NO</p> <p>Criteria ID: EX21A01 (For Pfizer use only):</p>	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1226

Subject No: 12261571

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 Exclusion Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:36:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX21A01	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-05-2020 16:37:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-05-2020 16:37:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-05-2020 16:37:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/5/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 68.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 169.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.1	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location FOREHEA :: D	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-05-2020 16:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-05-2020 16:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/5/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-05-2020 16:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 82803	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-07-2020 11:42:17 (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-07-2020 11:42:17 (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-07-2020 11:42:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-07-2020 11:42:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-07-2020 11:42:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-07-2020 11:42:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTJPM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Sep-07-2020 11:42:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTJPM	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-07-2020 11:42:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTJPN	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-07-2020 11:42:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTJPN	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-07-2020 11:42:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTJPP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-07-2020 11:42:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTJPP	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-07-2020 11:42:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHNWK	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-07-2020 11:42:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHNWK	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

5.e

Date	Location	User	Value	Reason
Sep-07-2020 11:43:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHNWL	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-07-2020 11:43:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHNWL	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-07-2020 11:28:13 (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-07-2020 11:28:13 (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-07-2020 11:28:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-07-2020 11:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-07-2020 11:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-07-2020 11:28:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTJP6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

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

Sep-07-2020 11:28:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTJP6	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-05-2020 16:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-05-2020 16:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-05-2020 16:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-05-2020 16:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/5/2020 15:08	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-05-2020 16:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-05-2020 16:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

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

7. Route:

Date	Location	User	Value	Reason
Sep-05-2020 16:42:59 (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
Sep-05-2020 16:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-05-2020 16:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-05-2020 16:43:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 14:24:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date:

Date	Location	User	Value	Reason
Sep-25-2020 14:24:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-25-2020 14:24:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location FOREHEA :: D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 14:24:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-25-2020 14:24:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 14:24:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-25-2020 14:24:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12261571

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

Buenos Aires

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 17:34:23 (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-25-2020 17:34:23 (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-25-2020 17:34:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 17:34:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 17:34:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 17:34:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP7X9X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

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

Sep-25-2020 17:34:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP7X9X	Initial Entry
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-25-2020 14:26:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-25-2020 14:26:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-25-2020 14:26:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-25-2020 14:26:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/25/2020 09:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 14:26:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-25-2020 14:26:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-25-2020 14:26:36 (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
Sep-25-2020 14:26:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 14:26:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-30-2020 03:38:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Closed as per site response, updated PD tracker for clinical review
Nov-27-2020 07:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	The date is correct. Subject came out of the window due unavailability.
Nov-27-2020 02:44:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 27 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Nov-26-2020 12:15:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Nov/2 6/202 0	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Nov-26-2020 16:51:45 (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-26-2020 16:51:45 (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-26-2020 16:51:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-26-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-26-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-26-2020 16:51:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR60GD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

Nov-26-2020 16:51:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR60GD	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-26-2020 16:52:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS2Y0N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-26-2020 16:52:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2Y0N	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-26-2020 16:52:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS2Y0P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-26-2020 16:52:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2Y0P	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-26-2020 12:15:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-26-2020 12:15:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-26-2020 12:15:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled **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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 17:44:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - 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: 12261571

Subject Initials: ---

Generated By: (b) (4)

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

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-11-2021 17:44:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

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Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (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-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excoriations in various regions of the body	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 17:48:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/30/2020 UNK:UNK	New Information
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

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Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (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-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (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 If Other, specify: hit by motorcycle	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 17:51:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-05-2020 17:51:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	New Information
Nov-05-2020 17:48:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Excoriations in various regions of the body: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 17:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261571**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (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-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bruises in various regions of the body	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 17:48:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/30/2020 UNK:UNK	New Information
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: C4591001

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Site No: 1226

Subject No: 12261571

Generated By: (b) (6)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (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-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (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 If Other, specify: hit by motorcycle	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Subject No: 12261571

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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

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Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 17:51:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-05-2020 17:51:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	New Information
Nov-05-2020 17:48:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Bruises in various regions of the body: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 17:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261571**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-27-2020 17:03:55 (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-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Peri-renal hematoma	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 17:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/30/2020 UNK:UNK	New Information
Oct-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: C4591001

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Site No: 1226

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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Oct-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-29-2020 09:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	recorded under AER2020418631
Oct-29-2020 09:25:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 06:08:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	SAE RECON: Pending PSSR confirmation if SAE form was receive
Oct-28-2020 16:17:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	As instructed by CRA, all the SAE were at the same document sent to Safety database. They are starting at page 3, and the name of the SAE is reported on item 10. The report was sent on 27/Oct /2020.
Oct-28-2020 06:59:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Peri-renal hematoma(Onset date:21Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF

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

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Oct-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Peri-renal hematoma: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-27-2020 17:03:55 (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/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	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-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:03:55 (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 If Other, specify: hit by motorcycle	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:03:55 (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-27-2020 17:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 17:03:55 (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-05-2020 17:51:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-05-2020 17:51:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information

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Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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Nov-05-2020 17:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Peri-renal hematoma: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-31-2020 11:05:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 11:21:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 11:21:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Transcription Error
Oct-30-2020 08:57:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020418631,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-27-2020 17:03:55 (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-27-2020 17:03:55 (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
Oct-29-2020 09:25:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020418631	Initial Entry

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261571**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-27-2020 17:05:03 (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-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subarachnoid hemorrhage	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 17:49:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/30/2020 UNK:UNK	New Information
Oct-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Oct-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-29-2020 09:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	recorded under AER2020418631
Oct-29-2020 06:08:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	SAE RECON: Pending PSSR confirmation if SAE form was receive
Oct-28-2020 16:17:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	As instructed by CRA, all the SAE were at the same document sent to Safety database. They are starting at page 3, and the name of the SAE is reported on item 10. The report was sent on 27/Oct/2020.
Oct-28-2020 07:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Oct-28-2020 06:59:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Subarachnoid hemorrhage(Onset date:21Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-27-2020 17:05:03 (UTC-03:00) City of	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Subarachnoid hemorrhage: Response

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Buenos Aires				to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-27-2020 17:05:03 (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/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	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-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Oct-30-2020 16:03:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thank you.
Oct-30-2020 07:42:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	information updated
Oct-29-2020 20:54:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per CRF Completion Guidelines section 8.50.2.1. "When an MVA results in an injury, both the injury and the MVA should be recorded as AEs." Please revise/update accordingly. Thank you.
Oct-27-2020 17:05:03 (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 If Other, specify: hit by motorcycle	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:05:03 (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-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Oct-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-05-2020 17:49:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-05-2020 17:49:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-05-2020 17:49:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Subarachnoid hemorrhage: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-31-2020 11:05:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 11:21:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 11:21:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Transcription Error
Oct-30-2020 08:58:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020418631,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-27-2020 17:05:03 (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?

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Date	Location	User	Value	Reason
Oct-27-2020 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-29-2020 09:25:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2020418631	Initial Entry

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Date	Location	User	Value	Reason
Oct-27-2020 17:05:57 (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-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fracture of the fourth cervical vertebra	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 17:50:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/30/2020 UNK:UNK	New Information
Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-02-2020 14:58:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Thank you.
Oct-30-2020 16:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	This information will be included in the next follow up
Oct-30-2020 16:04:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	If test was NOT done or NOT available, please submit FU report so this information is added to the case narrative as well. Thanks
Oct-30-2020 07:42:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Any SARS-CoV-2 test were performed
Oct-29-2020 20:59:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	Kindly confirm if any SARS-CoV-2 (NAAT or other) tests were performed on the SAE submitted to safety. If test performed = YES, please provide FU report with results. If test was NOT done or NOT available, please FU as well. Thanks
Oct-29-2020 09:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	recorded under AER2020418631

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Oct-29-2020 06:08:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	SAE RECON: Pending PSSR confirmation if SAE form was receive
Oct-28-2020 16:18:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	As instructed by CRA, all the SAE were at the same document sent to Safety database. They are starting at page 3, and the name of the SAE is reported on item 10. The report was sent on 27/Oct /2020.
Oct-28-2020 07:02:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Oct-28-2020 07:00:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Fracture of the fourth cervical vertebra(Onset date:21Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Fracture of the fourth cervical vertebra: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death?	Initial Entry

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			NO	
			Did this serious event require or pro long hospitalization?	
			YES	
			Did this serious event result in persi stent or significant disability/incapa city?	
			NO	
			Is this serious event life threatening ?	
			NO	
			Other medically important serious e vent	
			YES	

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-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER If Other, specify: hit by motorcycle	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Site No: 1226

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Generated By: (b) (4)

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

Subject Initials: ---

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Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020 17:05:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 17:05:57 (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-05-2020 17:50:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-05-2020 17:50:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-05-2020 17:50:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Fracture of the fourth cervical vertebra: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-31-2020 11:05:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 11:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 11:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Transcription Error

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Oct-30-2020 08:56:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020418631,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-27-2020 17:05:57 (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-27-2020 17:05:57 (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
Oct-29-2020 09:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020418631	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261571**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-27-2020 17:06:59 (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-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cervical spinal cord contusion	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 17:50:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/30/2020 UNK:UNK	New Information
Oct-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Oct-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-29-2020 09:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	recorded under AER2020418631
Oct-29-2020 06:08:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	SAE RECON: Pending PSSR confirmation if SAE form was receive
Oct-28-2020 16:17:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	As instructed by CRA, all the SAE were at the same document sent to Safety database. They are starting at page 3, and the name of the SAE is reported on item 10. The report was sent on 27/Oct /2020.
Oct-28-2020 07:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Oct-28-2020 07:00:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Cervical spinal cord contusion(Onset date:21Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF

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Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1226
Subject No: 12261571
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda
Subject Initials: ---
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Oct-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Cervical spinal cord contusion: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES 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/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	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-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-01-2020 05:49:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 07:43:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	information updated
Oct-29-2020 07:10:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [hit by motorcycle]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Oct-27-2020 17:06:59 (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> hit by motorcycle	Initial Entry

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Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-27-2020 17:06:59 (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-27-2020 17:06:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-27-2020 17:06:59 (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-05-2020 17:50:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-05-2020 17:50:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-05-2020 17:50:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Cervical spinal cord contusion: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-31-2020 11:05:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 11:22:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 11:22:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT	Transcription Error

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Header Text: C4591001

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Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Buenos Aires		(b) (4), (b) (6)	RESOLVED	
Oct-30-2020 08:56:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020418631,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-27-2020 17:06:59 (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-27-2020 17:06:59 (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
Oct-29-2020 09:25:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020418631	Initial Entry

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261571**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (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-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hit by motorcycle	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/21/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-02-2020 09:01:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	event recorded in SDB
Nov-02-2020 09:01:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-01-2020 12:00:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: hit by motorcycle is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE hit by motorcycle: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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			?	
			NO	
			Did this serious event require or pro long hospitalization?	
			YES	
			Did this serious event result in persi stent or significant disability/incapa city?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious e vent	
			YES	

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-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (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 If Other, specify: accidental	Initial Entry

10. Latest Action Taken with Study Treatment:

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (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-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 07:39:00 (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
Nov-02-2020 09:01:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020418631	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-11-2021 17:43:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-11-2021 17:43:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261571

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Nov-26-2020 12:15:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-05-2020 16:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-05-2020 16:37:20 (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-26-2020 12:15:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/26/2020	Initial Entry
Sep-05-2020 16:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/5/2020	Initial Entry
Sep-05-2020 16:37:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/5/2020	Initial Entry

090177e196ae4057\Final\Final On: 01-Apr-2021 05:37 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261571

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: ---

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-06-2020 14:56:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry