

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/14/2020
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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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Demography**

1.	Subject ID	[12311182]
2.	Birth Date:	(b) (6)/1957
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/14/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[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

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**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

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

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

**Exclusion Criteria**

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

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**Header Text:** C4591001

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**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

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**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

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(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

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

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**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

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

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**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

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**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

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**Generated Time (GMT):** 29-Mar-2021 16:45

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
2.1	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:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Arterial hypertension]
	Start Date:	Aug/10/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[obstructive sleep apneas]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/14/2020
2.	Weight:	[100.0]
3.	Unit:	kg
4.	Height:	[179.0]
5.	Unit:	cm
6.	Body Mass Index:	[31.2]

**Vital Signs Details**

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** RANDOMIZATION

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/14/2020
2.	Randomization Number:	[228483]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BLD3DJ]
5.b	Sample ID	[BLD3DK]
5.c	Sample ID	[BM8H1W]
5.d	Sample ID	[BM8H1X]
5.e	Sample ID	[BM8H1Y]
5.f	Sample ID	[BLD3DH]

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**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8H4B]
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/14/2020 11:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/4/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.2]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2780]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[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/4/2020 09:39
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 16:45

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**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12311182**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPXHD7]
5.b	Sample ID	[BLPHNW]
5.c	Sample ID	[BLPHPD]

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001**Visit:** V4\_MONTH6\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12311182**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BNTZ4J]
5.b	Sample ID	[BR23NJ]
5.c	Sample ID	[BNTZ59]



**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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:** 1231**Subject No:** 12311182**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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:** 1231**Subject No:** 12311182**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**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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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12311182**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Status:** Not Started**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45**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:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**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?	
----	--	--

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Illness Details**

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**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\_CONVA - New  
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12311182**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

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

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:**  
(b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231    **Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182    **Subject Initials:** ---

**Generated By:**    **Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Unplanned Assessments**

1.	Assessments	
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Disposition - Follow-Up**

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



**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12311182**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Vaccination**

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME - MONTH 1

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME - MONTH 6

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12311182**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12311182**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

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

Unscheduled

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Ischemic Stroke	Dec/7/2020 10:00	NO End Date Time:  Jan/10/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Ischemic Stroke]
4.	Start Date Time:	Dec/7/2020 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 UNK:UNK
6.	Toxicity Grade:	3

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12311182**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020493629]

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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**Medication Error**

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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**Concomitant Medications**

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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**Concomitant Medications**

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

**Header Text:** C4591001

**Visit:** UNPLANNED\_BOOSTER\_CONTACT  
- Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

**Booster Dose Trigger Form**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/5/2021
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:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Death Details**

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

**Cause of Death**

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



**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-03-2021 13:14:32 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

By my dated signature below, I, (b) (6), 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.

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6) [Redacted]	Approved	Mar-03-2021 13:14:32 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

By my dated signature below, I, (b) (6) [Redacted], verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6) [Redacted]	N/A	Mar-03-2021 10:35:46 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6) [Redacted]	Approved	Mar-03-2021 09:54:14 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Affidavit:**

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Mar-03-2021 09:22:13 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Mar-02-2021 16:30:01 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Affidavit:**

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Mar-02-2021 14:21:46 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Gonzalo Perez Marc	Approved	Feb-07-2021 20:37:47 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-05-2021 12:52:16 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Jan-29-2021 15:33:58 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Affidavit:**

By my dated signature below, I, (b) (6), 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	Jan-27-2021 10:44:33 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Vanesa Fainboim	Approved	Jan-20-2021 18:50:18 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Affidavit:**

By my dated signature below, I, VanesaFainboim, 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	Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Fernando Polack	Approved	Oct-12-2020 16:55:22 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

**Affidavit:**

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

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

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

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-14-2020 12:37:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:37:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Consent Was:*

Date	Location	User	Value	Reason
Aug-14-2020 12:37:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consequence Obtained  Aug/14/2020	Initial Entry

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-14-2020 09:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12311182	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-14-2020 09:21:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1957	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-14-2020 12:37:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-14-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

12:37:26 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	HISPANIC OR LATI NO(A) OR OF SPAN ISH ORIGIN
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-14-2020 12:37:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-14-2020 12:38:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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*I.a*

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Incl 1 usio n N um ber:</b></p> <p><b>Crit Male or female erio participants bet n D ween the ages o escr f 18 and 55 yea ipti rs, inclusive, 65 on: and 85 years, in clusive, or 18 a nd 85 years, inc lusive, at rando mization (depe ndent upon stud y stage)</b></p> <p><b>Crit YES erio n m et?:</b></p>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)



**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

			<b>Crit IN01A00 erion ID : (F or P fize r us e on ly):</b>	
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***1.a Inclusion Number:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

***1.a Criterion Description:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female partici pants between the age s of 18 and 55 years, i nclusive, 65 and 85 ye ars, inclusive, or 18 a nd 85 years, inclusive, at randomization (dep endent upon study sta ge)	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

***1.a Criterion met?***

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN01A00	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Incl 2 usio n N umb er:	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

			<p><b>Crit</b> Participants wh <b>erio</b> o are willing an <b>n De</b> d able to compl <b>scri</b> y with all sche <b>ptio</b> duled visits, va <b>n:</b> ccination plan, laboratory tests , lifestyle consi derations, and other study pro cedures</p> <p><b>Crit</b> YES <b>erio</b> <b>n m</b> <b>et?:</b></p> <p><b>Crit</b> IN02A00 <b>erio</b> <b>n ID</b> <b>: (Fo</b> <b>r Pfi</b> <b>zer</b> <b>use</b> <b>only</b> <b>):</b></p>	
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**1.b Inclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**1.b Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participants who are willing and able to co mply with all schedul ed visits, vaccination plan, laboratory tests, lifestyle consideration s, and other study pro cedures	Initial Entry

**1.b Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN02A00	Initial Entry

*1.c*

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <b>Incl 3 usio n N umb er:</b>  <b>Crit</b> Healthy partici <b>erio</b> pants who are d <b>n De</b> etermined by m <b>scri</b> edical history, <b>ptio</b> physical exami <b>n:</b> nation, and clin ical judgment o f the investigat or to be eligible for inclusion in the study  <b>Crit</b> YES <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

			<b>Crit IN03A00 erio n ID : (Fo r Pfi zer use only ):</b>	
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**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

***I.c Inclusion Number:***

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

***I.c Criterion Description:***

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Healthy participants who are determined b y medical history, phy sical examination, and clinical judgment of t he investigator to be e ligible for inclusion in the study	Initial Entry

***I.c Criterion met?***

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN03A00	Initial Entry

*1.d*

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <b>Incl 4</b> <b>usio</b> <b>n Nu</b> <b>mbe</b> <b>r:</b>  <b>Crit</b> Capable of givi <b>erio</b> ng personal sig <b>n De</b> ned informed c <b>scri</b> onsent, which i <b>ptio</b> ncludes compli <b>n:</b> ance with the r requirements an d restrictions li sted in the ICD and in this prot ocol  <b>Crit</b> YES <b>erio</b> <b>n me</b> <b>t?:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)



**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

			<b>Crit IN04A00</b>	
			<b>erio</b>	
			<b>n ID</b>	
			<b>: (Fo</b>	
			<b>r Pfi</b>	
			<b>zer</b>	
			<b>use</b>	
			<b>only</b>	
			<b>):</b>	

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

***1.d Inclusion Number:***

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

***1.d Criterion Description:***

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Capable of giving per sonal signed informed consent, which includ es compliance with th e requirements and re strictions listed in the ICD and in this protoc ol	Initial Entry

***1.d Criterion met?***

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <b>Excl 1</b> <b>usio</b> <b>n N</b> <b>umb</b> <b>er:</b>  <b>Crit</b> Other medical <b>erio</b> or psychiatric c <b>n De</b> ondition incl. r <b>scri</b> ecent (within p <b>ptio</b> ast year) or acti <b>n:</b> ve suicidal idea tion/behavior/la b abnormality t hat may increas e the risk of stu dy participation  <b>Crit</b> NO <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

			<b>Crit EX01A00 erion ID : (F or P fizer use only ):</b>	
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**2.a Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Other medical or psyc hiatric condition incl. recent (within past ye ar) or active suicidal i deation/behavior/lab a bnormality that may i ncrease the risk of stu dy participation	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**2.a Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX01A00	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclu 2</b> <b>sion</b> <b>Num</b> <b>ber:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

			<p><b>Crite rion</b> Known infecti on with huma <b>Descr n</b> immunodef iption ciency virus ( <b>n:</b> HIV), hepatiti s C virus (HC V), or hepatiti s B virus (HB V)</p> <p><b>Crite rion</b> NO <b>met?:</b></p> <p><b>Crite rion I</b> EX02A00 <b>D: (F</b> <b>or Pfi</b> <b>zer u</b> <b>se onl</b> <b>y):</b></p>	
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Header Text: C4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

**2.b Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**2.b Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Known infection with human immunodefici ency virus (HIV), hep atitis C virus (HCV), or hepatitis B virus (H BV)	Initial Entry

**2.b Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX02A00	Initial Entry
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2.c

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Excl 3 usio n Nu mbe r: Crit History of severe erio re adverse reac n De tion associated scri with a vaccine ptio and/or severe a n: llergic reaction (eg, anaphylaxi s) to any comp onent of the stu dy intervention (s)  Crit NO erio n me t?:	Initial Entry

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**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

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			<b>Crit EX03A00</b>	
			<b>erio</b>	
			<b>n ID</b>	
			<b>: (Fo</b>	
			<b>r Pfi</b>	
			<b>zer</b>	
			<b>use</b>	
			<b>only</b>	
			<b>):</b>	

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Subject Initials: ---

Generated By:

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(b) (4)

**2.c Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**2.c Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> History of severe adv erse reaction associate d with a vaccine and/ or severe allergic reac tion (eg, anaphylaxis) to any component of t he study intervention( s)	Initial Entry

**2.c Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX03A00	Initial Entry

*2.d*

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 4 <b>Criterion Description:</b> Receipt of medication intended to prevent COVID-19 <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX04A00	Initial Entry

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**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

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**Subject Initials:** ---

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(b) (4)

**2.d Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

**2.d Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medication s intended to prevent COVID-19	Initial Entry

**2.d Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

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**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

of Buenos Aires

2.e

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Excl 8</b></p> <p><b>usio</b></p> <p><b>n Nu</b></p> <p><b>mbe</b></p> <p><b>r:</b></p> <p><b>Crit Immunocompr</b></p> <p><b>erio omised individ</b></p> <p><b>n De uals with know</b></p> <p><b>scrip n or suspected</b></p> <p><b>tion: immunodeficie</b></p> <p>ncy, as determi</p> <p>ned by history</p> <p>and/or laborato</p> <p>ry/physical exa</p> <p>mination</p> <p><b>Crit NO</b></p> <p><b>erio</b></p> <p><b>n me</b></p> <p><b>t?:</b></p>	Initial Entry

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**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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Mayor Dr. Cosme Argerich

**Subject Initials:** ---

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			<b>Crit</b> EX08A00	
			<b>erio</b>	
			<b>n ID</b>	
			<b>: (Fo</b>	
			<b>r Pfi</b>	
			<b>zer u</b>	
			<b>se on</b>	
			<b>ly):</b>	

Header Text: C4591001

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Site Name: (1231) Hospital Militar Central Cirujano  
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Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 8	Initial Entry

**2.e Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immunocompromised individuals with know n or suspected immun odeficiency, as determ ined by history and/or laboratory/physical ex amination	Initial Entry

**2.e Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX08A00	Initial Entry
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2.f

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Excl 10 usio n Nu mbe r: Crit Bleeding diath erio esis or conditio n De n associated wi scrip th prolonged bl tion: eeding that wo uld, in the opin ion of the inves tigator, contrai ndicate intram uscular injectio n Crit NO erio n me t?:	Initial Entry

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**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

			<b>Crit EX10A00</b> <b>erio</b> <b>n ID</b> <b>: (Fo</b> <b>r Pfi</b> <b>zer</b> <b>use</b> <b>only</b> <b>):</b>	
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Header Text: C4591001

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Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

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(b) (4)

**2.f Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 10	Initial Entry

**2.f Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bleeding diathesis or condition associated with prolonged bleedi ng that would, in the opinion of the investi gator, contraindicate i ntramuscular injection	Initial Entry

**2.f Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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**Subject Initials:** ---

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(b) (4)

Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry
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2.g

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Women who are pregnant or breastfeeding <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX11A00	Initial Entry

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Mayor Dr. Cosme Argerich

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**Subject Initials:** ---

**Generated By:**

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(b) (4)

**2.g Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11	Initial Entry

**2.g Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are preg nant or breastfeeding	Initial Entry

**2.g Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX11A00	Initial Entry

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(b) (4)

of Buenos Aires

**2.h**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 12 <b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX12A00	Initial Entry

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**Subject Initials:** ---

**Generated By:**

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(b) (4)

**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

**2.h Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX12A00	Initial Entry

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**Subject Initials:** ---

**Generated By:**

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**2.i**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX13A01 <b>For Pfizer use only:</b>	Initial Entry

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**Subject Initials:** ---

**Generated By:**

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(b) (4)

**2.i Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13	Initial Entry

**2.i Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subjects who receive immunosuppressive t herapy, such as cyto toxic agents or systemic corticosteroids	Initial Entry

**2.i Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry
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2.j

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Excl 15 usio n Nu mbe r: <b>Crit</b> Receipt of bloo <b>erio</b> d/plasma produ <b>n De</b> cts or immuno <b>scrip</b> globulin, from <b>tion:</b> 60 days before study intervent ion administrat ion or planned receipt through out the study  <b>Crit</b> NO <b>erio</b> <b>n me</b> <b>t?:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

				<b>Crit EX14A01</b>	
				<b>erio</b>	
				<b>n ID</b>	
				<b>: (Fo</b>	
				<b>r Pfi</b>	
				<b>zer u</b>	
				<b>se on</b>	
				<b>ly):</b>	

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

**2.j Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

**2.j Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

**2.j Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX14A01	Initial Entry
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

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(b) (4)

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2.k

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Exclusion Number:</b> 16</p> <p><b>Criterion:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID: (For Pfizer use only):</b> EX15A01</p>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

**2.k Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

**2.k Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participation in other studies involving stud y intervention within 28 days prior to study entry and/or during st udy participation	Initial Entry

**2.k Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX15A01	Initial Entry
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**2.1**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclu 17</b> <b>sion</b> <b>Num</b> <b>ber:</b> <b>Crite</b> Previous part <b>ri</b> icipation in ot <b>on</b> her studies in <b>Descr</b> volving study <b>ption</b> : intervention c ontaining lipi d nanoparticl es <b>Crite</b> NO <b>ri</b> <b>on</b> <b>met?:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

			<b>Crite</b> EX16A01 <b>rion I</b> <b>D: (F</b> <b>or Pfi</b> <b>zer us</b> <b>e only</b> <b>):</b>	
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

**2.1 Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 17	Initial Entry

**2.1 Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous participation in other studies invol ving study interventio n containing lipid nan oparticles	Initial Entry

**2.1 Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.1 Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX16A01	Initial Entry
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*2.m*

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Excl 22 usio n N umb er: Crit Investigator sit erio e staff or Pfizer n D employees dire escr ctly involved i iptio n the conduct o n: f the study, site staff otherwise supervised by t he investigator, and their respe ctive family m embers  Crit NO erio n m et?:	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

			<b>Crit EX21A01 erion ID : (F or P fizer use only ):</b>	
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

**2.m Exclusion Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 22	Initial Entry

**2.m Criterion Description:**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Investigator site staff or Pfizer employees d irectly involved in the conduct of the study, site staff otherwise su pervised by the invest igator, and their respe ctive family members	Initial Entry

**2.m Criterion met?**

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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**Header Text:** C4591001

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

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

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-14-2020 12:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX21A01	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

Date	Location	User	Value	Reason
Aug-14-2020 12:40:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-14-2020 12:40:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-14-2020 12:40:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1.a*

Date	Location	User	Value	Reason
Aug-14-2020 12:42:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical Hi</b> Arterial h <b>story Term</b> ypertensi : on <b>Start Date:</b> Aug/10/2 005 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-14-2020 12:42:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 21:25:57 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

of Buenos Aires				
Dec-15-2020 17:22:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The antecent load has already been carried out. Thank you
Dec-15-2020 11:14:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL On review of the SAE report for Stroke, Med history of apnea requiring CPAP has been mentioned, yet it does not appear in the CRF. Please review for clinical relevance to safety event and update Med Hx log CRF if appropriate.
Aug-14-2020 12:42:53 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Arterial hypertension	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)



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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

of Buenos Aires

**1.a Start Date:**

Date	Location	User	Value	Reason
Aug-14-2020 12:42:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/10/2005	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Aug-14-2020 12:42:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Dec-15-2020 17:21:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 2 <b>Number:</b> <b>Medical History Term:</b> obstructive sleep apnea <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Dec-15-2020 17:21:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Dec-15-2020 17:21:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> obstructive sleep apne as	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Dec-15-2020 17:21:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Dec-15-2020 17:21:59 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

of Buenos Aires

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Date:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 100.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 179.0	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 31.2	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 36.7	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

			<b>Temperatu C re Unit:</b> <b>Temperatu ORAL re Location CAVIT :: Y</b>	
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.7	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-14-2020 12:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-14-2020 12:46:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-14-2020 12:46:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 228483	Initial Entry



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-14-2020 12:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-14-2020 12:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-14-2020 18:51:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 12:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

				are entered. Please review and correct as appropriate.
Aug-14-2020 12:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Aug/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-14-2020 18:51:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BLD3D : J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 18:51:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLD3DJ	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 18:51:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BLD3D : K	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 18:51:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLD3DK	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-14-2020 18:52:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BM8H1 <b>D:</b> W	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 18:52:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8H1W	Initial Entry

**5.d**

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-14-2020 18:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM8H1 : X	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 18:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8H1X	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-14-2020 18:52:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM8H1 : Y	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 18:52:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8H1Y	Initial Entry

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**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**5.f**

Date	Location	User	Value	Reason
Aug-20-2020 12:48:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<b>Data Entry:</b> Sample I BLD3D D: H	Initial Entry

**5.f Sample ID**

Date	Location	User	Value	Reason
Aug-20-2020 12:48:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<b>Data Entry:</b> BLD3DH	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-14-2020 12:46:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-14-2020 12:46:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-14-2020 18:50:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 12:46:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

				are entered. Please review and correct as appropriate.
Aug-14-2020 12:46:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Aug/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-14-2020 18:50:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BM8H4 : B	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 18:50:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM8H4B	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

Date	Location	User	Value	Reason
Aug-14-2020 12:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-14-2020 12:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-14-2020 12:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-14-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

12:47:30  
(UTC-03:00) City  
of Buenos Aires

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

Aug/14/2020 11:40

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-14-2020 12:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-14-2020 12:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-14-2020 12:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

Date	Location	User	Value	Reason
Aug-14-2020 12:47:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-14-2020 12:47:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGEN ICITY E-DIARY CO LLECTED FOR THI S SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-04-2020 11:01:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/4/2020	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the l</b> <b>ast day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry

<b>2.b Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry
<b>2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
<b>2.c</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or sy NO</b> <b>stemic symptom</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

<b>2.c Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry
<b>2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
<b>2.d</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI L LS  <b>Were fever or sy N</b> <b>stemic symptoms O</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry



<b>2.d Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry
<b>2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
<b>2.e</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG <b>Were fever or sy NO</b> <b>stemic symptom</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

<b>2.e Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry
<b>2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
<b>2.f</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

<b>2.f Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry
<b>2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
<b>2.g</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUSC LE PA IN  <b>Were fever o</b> NO <b>r systemic sy</b> <b>mptoms pres</b> <b>ent on the las</b> <b>t day the Sub</b> <b>ject Diary w</b> <b>as completed</b> <b>?:</b>	Initial Entry

<b>2.g Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D MUSCLE PAIN	Initial Entry
<b>2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
<b>2.h</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED J OINT PAIN  <b>Were fever o</b> NO <b>r systemic sy</b> <b>mptoms pres</b> <b>ent on the las</b> <b>t day the Sub</b> <b>ject Diary wa</b> <b>s completed?</b> :	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Re RE</b> <b>action::</b> D NE SS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction: SW EL LI NG  Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

<b>5.b Injection Site Reaction:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry
<b>5.b Were injection site reactions present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
<b>5.c</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site</b> PAIN <b>Reaction::</b> AT I NJE CTI ON S ITE  <b>Were injection</b> NO <b>site reactions</b> <b>present on the</b> <b>last day the Su</b> <b>bject Diary w</b> <b>as completed?</b> :	Initial Entry

**5.c Injection Site Reaction:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-04-2020 11:02:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Date:**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/4/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 37.2 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:31 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

of Buenos Aires

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.2	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-04-2020 11:02:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-04-2020 14:22:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-04-2020 11:50:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

				are entered. Please review and correct as appropriate.
Sep-04-2020 11:02:41 (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-04-2020 11:02:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-04-2020 14:22:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP278 : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Sep-04-2020 14:22:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2780	Initial Entry
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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

Date	Location	User	Value	Reason
Sep-04-2020 11:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-04-2020 11:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-04-2020 11:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-04-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

11:03:09  
(UTC-03:00) City  
of Buenos Aires

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

Sep/4/2020 09:39

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-04-2020 11:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-04-2020 11:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-04-2020 11:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Sep-04-2020 11:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

Date	Location	User	Value	Reason
Sep-04-2020 11:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)



**Header Text:** C4591001

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-09-2020 05:22:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 16:15:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The form in question is already loaded. Thank you.
Oct-07-2020 23:33:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Opened	DM: Per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination (Visit 3 date). As Visit 3 is now reached,

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4) [Redacted]

				please complete the EOT form accordingly.
Oct-02-2020 11:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Oct/2/2020	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

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

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the l</b> <b>ast day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry

<b>2.b Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> FATIGUE	Initial Entry
<b>2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry
<b>2.c</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or sy NO</b> <b>stemic symptom</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

<b>2.c Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> HEADACHE	Initial Entry
<b>2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry
<b>2.d</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> <b>Symptom::</b> C HI L LS  <b>Were fever or sy N</b> <b>stemic symptoms O</b> <b>present on the la</b> <b>st day the Subjec</b> <b>t Diary was com</b> <b>pleted?:</b>	Initial Entry

<b>2.d Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> CHILLS	Initial Entry
<b>2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry
<b>2.e</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG <b>Were fever or s</b> NO <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the S</b> <b>ubject Diary wa</b> <b>s completed?:</b>	Initial Entry

<b>2.e Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> VOMITING	Initial Entry
<b>2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry
<b>2.f</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry



**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUSC LE PA IN  <b>Were fever o</b> NO <b>r systemic sy</b> <b>mptoms pres</b> <b>ent on the las</b> <b>t day the Sub</b> <b>ject Diary w</b> <b>as completed</b> <b>?:</b>	Initial Entry

<b>2.g Symptom:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NEW OR WORSENE D MUSCLE PAIN	Initial Entry
<b>2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry
<b>2.h</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED J OINT PAIN  <b>Were fever o</b> NO <b>r systemic sy</b> <b>mptoms pres</b> <b>ent on the las</b> <b>t day the Sub</b> <b>ject Diary wa</b> <b>s completed?</b> :	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> RIGHT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> <b>Injection Site Re RE</b> <b>action::</b> D NE SS	Initial Entry

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

<b>5.a Injection Site Reaction:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<b>Data Entry:</b> REDNESS	Initial Entry

<b>5.a Were injection site reactions present on the last day the Subject Diary was completed?</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<b>Data Entry:</b> NO	Initial Entry

<b>5.b</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW EL LI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) [REDACTED] (6) [REDACTED]	<b>Data Entry:</b> <b>Injection Site</b> PAIN <b>Reaction::</b> AT I NJE CTI ON S ITE  <b>Were injection</b> NO <b>site reactions</b> <b>present on the</b> <b>last day the S</b> <b>ubject Diary</b> <b>was complete</b> <b>d?:</b>	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-02-2020 12:28:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-02-2020 12:28:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-02-2020 16:28:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 12:28:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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: 1231 Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12311182 Subject Initials: ---

Generated By: Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-02-2020 12:28:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-02-2020 16:28:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BPXHD D: 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 16:28:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPXHD7	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (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: 1231 Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12311182 Subject Initials: ---

Generated By: Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Oct-02-2020 16:52:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample I</b> BLPHN <b>D:</b> W	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 16:52:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BLPHNW	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-02-2020 17:18:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BLPHP : D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 17:18:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLPHPD	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-02-2021 14:21:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/2/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

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

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-02-2021 14:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-02-2021 14:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-02-2021 15:59:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 14:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

				are entered. Please review and correct as appropriate.
Mar-02-2021 14:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/2/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-02-2021 15:59:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BNTZ4 : J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-02-2021 15:59:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNTZ4J	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_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:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Mar-03-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR23N <b>D:</b> J	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR23NJ	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-03-2021 10:35:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNTZ5 <b>D:</b> 9	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 10:35:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNTZ59	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

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

Date	Location	User	Value	Reason
Oct-08-2020 15:14:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Carolina Bonacossa (b) (4)	<b>Data Entry:</b> Oct/2/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-08-2020 15:14:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-08-2020 15:14:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Carolina Bonacossa (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-05-2021 12:52:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182 **Subject Initials:** ---

**Generated By:** **Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

Date	Location	User	Value	Reason
Feb-05-2021 12:52:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 12:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-05-2021 12:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willin g to return for Vacc ination 3 Participant is:  eligible and NO T confirmed to h ave received onl	Initial Entry

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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**1. Category:**

Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-22-2021 19:12:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-15-2021 13:10:26 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	In the initial report, 3 days of hospitalization were

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

City of Buenos Aires				recorded and both in the initial bullet 30 and in the FU of 16DEC it is clarified that the man entered on 7DEC, left the same day and then re-entered 8DEC by progression of symptoms until 9DEC2020.
Jan-12-2021 23:20:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINICAL The SAE narrative states subject was in hospital for 3 days; recognizing that he was discharged and readmitted for the same event, please report hospital start and end for the entire period.
Dec-26-2020 11:44:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The volunteer is admitted on 12/7/20 and is external that same day. He re-entered 12/8/20 and remains hospitalized until 12/9/20. He was not

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

				hospitalized from 12/7 to 12/9. SAE followup sent. Thank you.
Dec-23-2020 21:58:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical In SAE report under Event section for SAE ischemic stroke, the hospitalization Start/End dates are both 07Dec20. Could the hospital dates in the SAE Event section be updated to Start 07Dec/End 09Dec, in a safety followup.
Dec-20-2020 19:05:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject was admitted and discharged on 07 Dec 2020. As symptoms persisted, subject was readmitted on 08 Dec 2020 until 9 Dec 2020. This information was sent in SAE report on 16Dec20.

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

Dec-18-2020 14:12:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical SAE report on 16Dec20 has the discharge date of 09Dec20 in the narrative; however, Hospitalization details for event of Pericarditis has admission/discharge on 09Dec20
Dec-18-2020 11:49:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The Hosp end date to 09Dec20 was updated in the follow up form on 16DEC2020. Thank you.
Dec-17-2020 14:27:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical Thank you. If reporting both hospitalizations for SAE pericarditis, please update the Hosp end date to 09Dec20
Dec-16-2020 17:39:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The Subject was admitted to the hospital on Dec 7, 2020 and discharged the same day. Due to persistence of

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

				symptoms, he was readmitted from Dec 8, 2020 to Dec 9, 2020. Event update form sent to sponsor. Thank you.
Dec-15-2020 21:25:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical SAE report for event Ischemic Stroke reports hospitalization from 07Dec to 07Dec; however, SAE narrative states hospitalization occurred overnight from 08Dec to 09Dec. Please review, & update as required.
Dec-15-2020 11:03:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 10:44:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE Initial reporting Form was sent on 12DIC2020

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Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12311182

Subject Initials: ---

Generated By:

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(b) (4)

Dec-14-2020 12:49:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 1: Opened	GPD Clin: AE Ischemic Stroke is indicated as serious and subject was admitted to the hospital. Please submit Serious Adverse Event form to the Pfizer Safety reporting system as per requirements ASAP.
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ischemic Stroke	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/7/2020 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-02-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response

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**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

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**Subject Initials:** ---

**Generated By:**

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(b) (4)

16:39:45 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		satisfies query
Jan-29-2021 12:22:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Clarify that considering that the symptoms are minimum and the event started 7 weeks ago, we consider the SAE status as recovered with mild sequelae. We'll continue to follow up the subject's symptoms, and in case the symptoms resolve we'll sent FU.
Jan-27-2021 19:03:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical End date 10Jan21; however, SAE report has no end date and neurologist states improvement

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**Subject Initials:** ---

**Generated By:**

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(b) (4)

				continues/may continue for 3 months. Harmonize End date reporting; either remove on AE or add to SAE
Jan-27-2021 10:44:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/10/2021 U NK:UNK	New Information
Jan-22-2021 19:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-17-2021 18:03:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It is clarified that the hypoesthesia symptom is in slight improvement. In consultation with the neurologist, he clarifies that these symptoms

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**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

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**Subject Initials:** ---

**Generated By:**

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(b) (4)

				can persist for three months (only one month has elapsed)
Jan-12-2021 23:25:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical SAE report states subj has persistent hypoaesthesia of lip, chin & Lt fingers as of 30Dec20. Please consider if event of Ischemic Stroke has now resolved with sequellae, and update if appropriate
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-17-2020 09:16:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-15-2020 21:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-15-2020 17:18:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	During the hospitalization, a covid test was not performed because the AE

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

				is not related to covid disease. Follow up was sent on 12/12/2020
Dec-15-2020 11:23:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2020493629] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Ischemic Stroke: Response to "Is the adverse event serious?" is 'Yes' but "Serious

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

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**Subject Initials:** ---

**Generated By:**

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(b) (4)

				Adverse Event Number" is blank.
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>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>	Initial Entry

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

			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.*

Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

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(b) (4)

			OTHER	
			<i>If Other, specify:</i>	
			history of arterial hypertension	

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-15-2020 21:22:40 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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**Subject Initials:** ---

**Generated By:**

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(b) (4)

City of Buenos Aires				
Dec-15-2020 17:20:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Non-pharmacological treatment: low sodium diet
Dec-15-2020 11:14:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Please clarify the non-drug treatment given for SAE Ischemic Stroke
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-27-2021 10:44:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-27-2021 10:44:46 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/ RESOLVED W	New Information

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

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(b) (4)

City of Buenos Aires			ITH SEQUELA E	
Jan-27-2021 10:44:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Ischemic Stroke: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING /RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-13-2020 18:33:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Dec-17-2020 09:16:17 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020493629	Initial Entry

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**Header Text:** C4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

of Buenos Aires

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**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-05-2021 12:52:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-05-2021 12:52:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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*1. Subject Status*

Date	Location	User	Value	Reason
Oct-08-2020 15:14:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-14-2020 12:46:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDO MIZED	Initial Entry
Aug-14-2020 12:40:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

*2. Subject Status Date*

Date	Location	User	Value	Reason
Oct-08-2020 15:14:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/2/2020	Initial Entry
Aug-14-2020 12:46:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject No:** 12311182

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aug-14-2020 12:40:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/14/2020	Initial Entry
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**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1231

**Subject No:** 12311182

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-12-2020 16:55:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Fernando Polack (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae2f13\Final\Final On: 01-Apr-2021 03:33 (GMT)